

Confidentiality Agreement

This Agreement (hereinafter referred to as the "Agreement") is made and entered into by and between [INSTITUTION NAME], with its registered office at [ADDRESS] (hereinafter referred to as the "Institution") and [COMPANY NAME], a company incorporated in [COUNTRY] with its registered office at [ADDRESS] (hereinafter referred to as the "Discussion Party") with respect to the handling of the disclosed information as follows:

Article 1: Purpose

- 1 Institution and Discussion Party desire to explore potential opportunities for [handling of the information disclosed between the parties during performance of the review of plans to conduct the clinical trial: [STUDY NAME] (hereinafter referred to as the "Study").

Article 2: Confidential Information

1 "Confidential Information" shall mean the following:

- (1) Information disclosed by one party to this Agreement (hereinafter, the party disclosing information shall be referred to as the "Disclosing Party" and the party receiving information shall be referred to as the "Receiving Party") on a confidential or equivalent basis.
- (2) In addition to what is provided for in the preceding item, information disclosed orally by the Information Disclosing Party that is specified in a document issued by the Information Disclosing Party that has been notified that the information is confidential prior to or at the time of disclosure and that shows that the location, date, and contents of disclosure of the information concerned are concisely described as confidential within thirty days after said disclosure.
- (3) In addition to what is provided for in the preceding two items, the confidentiality of which can be reasonably and objectively judged.

2 Notwithstanding the provisions of the preceding paragraph, information falling under any of the following items shall not fall under Confidential Information.

- (1) Information already in the possession of the Information Receiver upon disclosure by the Information Disclosing Party
- (2) Information already in the public domain when disclosed by the Disclosing Party
- (3) Information that has become publicly known through no fault of the information recipient after disclosure by the information disclosing party
- (4) Information for which prior written consent is obtained from the Information Disclosing Party to exclude such information from the Confidential Information
- (5) Information lawfully obtained by the Information Receiver from a duly authorized third party without any obligation of confidentiality
- (6) Information independently developed or acquired by the Information Receiver without reference to information disclosed by the Information Disclosing Party.

3 In the event the receiving party is obliged to disclose the Confidential Information of the other party by law or ordinance or by the competent government agency, court, or other public organization, or in the event the receiving party receives a request for disclosure from the relevant authority, the receiving party may immediately notify the other party to that effect and disclose the same to the relevant competent government agency, court, or relevant authority to the extent necessary and reasonable, provided that the receiving party takes the measures set forth in the following items:

- (1) Notify the Disclosing Party of the contents of the Confidential Information to be disclosed in advance.
- (2) When disclosing the Confidential Information, the fact that such Confidential Information is confidential shall be clearly indicated on the media by means of a confidential indication, etc.

Article 3: Confidentiality and Prohibition of Use for Other Purposes

1 Receiving Party shall manage the Confidential Information as confidential and shall not disclose or divulge it to

any third party without the prior written consent of the Information Disclosing Party. Provided, however, that Receiving Party may disclose the Confidential Information to its affiliates as set forth below to the minimum extent necessary for the Study.

(1) [AFFILIATES]

(2) [AFFILIATES]

2 Receiving Party and its affiliates shall not use the Confidential Information for any purpose other than the Study.

Article 4: Management of Confidential Information

1 With regard to the handling of confidential information, either party shall appoint a responsible person as follows and shall promptly notify the other party in writing of any change in the responsible person.

(1) Institution: Dr. XXX

[DEPARTMENT], [INSTITUTION NAME]

[TITLE]

(2) Discussion Party:

[NAME]

[DEPARTMENT], [COMPANY NAME]

[TITLE]

2 Institution and Discussion Party shall be entitled to disclose the Confidential Information only to the officers and employees involved in the Study (hereinafter referred to as the "Employees") to the extent necessary and reasonable for the Employees to participate in the Study. In addition, Institution and Discussion Party shall have the employees disclosing the Confidential Information observe the same obligations under this Agreement as they do under this Agreement during their tenure of employment and after retirement.

Article 5: Prohibition of Reproduction

1 The information recipient shall not reproduce the Confidential Information, in whole or in part, beyond the extent necessary to carry out the Study.

2 Reproductions of Confidential Information shall be treated as Confidential Information under this Agreement.

Article 6: Return of Confidential Information

1 Upon the expiration of the Study Period or upon request of the Information Disclosing Party, the Information Receiving Party shall return to the Disclosing Party, without delay, documents, electronic media, other tangible objects, and electronic data containing confidential information (including reproductions in the event such reproductions are reproduced in any way) or delete or destroy them in accordance with the instructions of the Disclosing Party.

Article 7: Handling of Related Inventions

1 In the event any invention, device, or any other technical result subject to intellectual property rights is obtained in the course of conducting the Study, such technical result (hereinafter referred to as the "Related Inventions") shall be disclosed to the other party without delay, and neither party shall file an application for the registration of the establishment of the Intellectual Property Rights without prior written consent of the other party. In addition, neither party hereto shall disclose or provide to any third party any information or materials including related inventions without obtaining the prior written consent of the other party.

2 The attribution of the property rights (including the right to obtain a patent and other intellectual property rights) to the related Inventions disclosed pursuant to the preceding paragraph shall be determined separately after due consultation between Institution and Discussion Party.

Article 8: No Warranty

1 Institution acknowledges that Discussion Party does not guarantee the accuracy or completeness of Discussion Party's own confidential information. Therefore, Discussion Party shall not be liable for any defect in the use of the Confidential Information by Institution or in the accuracy or completeness of the Confidential Information.

Article 9: Handling of Tradability

1 The conclusion of this Agreement shall not create any legal obligation to Institution and Discussion Party with respect to the possibility of a transaction that is the subject of the Study. In the event of the commencement of such transactions, Institution and Discussion Party shall conclude a separate agreement that clearly stipulates the rights and obligations.

Article 10: Compensation for Damages

1 In the event the Information Receiver violates any provision of this Agreement (including persons similar to Institution as set forth in Paragraph 2 of Article 4 of this Agreement, hereinafter the same shall apply in this Article), the Information Disclosing Party shall be entitled to suspend such violation and claim compensation for damages incurred from the Information Receiver. In addition, in the event a claim for damages is filed by a third party against the Information Disclosing Party due to a breach by the Information Receiving Party of the provisions of this Agreement, the Information Receiving Party shall settle the matter at its own cost and responsibility and shall not cause any inconvenience to the Information Disclosing Party.

Article 11: Prohibition of Assignment of Rights and Obligations

1 Neither party may assign its rights or obligations under this Agreement to a third party without the prior written consent of the other party.

Article 12: Compliance Rules

1 In entering into this Agreement and implementing this Agreement, Institution shall confirm that the relevant regulations are met by obtaining the necessary notification and approval in accordance with the hospital regulations to which Institution belongs.

Article 13: Term of Agreement

1 This Agreement shall become effective on the date of its execution and shall remain in force for a period of five (5) years from the day following the date of termination of the Study Period pursuant to any of the provisions of Article 6 hereof.

Article 14: Consultation

1 Any matter not stipulated in this Agreement or any doubtful point arising in this Agreement shall be discussed in good faith between Institution and Discussion Party.

Article 15: Governing Law and Jurisdiction

1 The formation and effect of the Agreement shall be governed by the laws of Japan. The Agreement shall be construed and performed in accordance with the laws of Japan, and all disputes which may arise between the parties out of or in connection with this Agreement shall be settled by the district courts located within the city in which the defendant is located.

(Signature Page Follows)

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed in duplicate by their authorized representatives, hereunto set their hands and seals, each party retaining one (1) copy thereof, respectively.

Signed
For and on behalf of
[INSTITUTION NAME]

By: _____
Name: _____
Title: _____
Date: _____

Signed
For and on behalf of

By: _____
Name: _____
Title: _____
Date: _____