



กองบริหารงานวิจัย มหาวิทยาลัยมหิดล
โทร.0-2849-6254 โทรสาร 0-2849-6054

ที่ อว 78.016/ ๒๒๖/

วันที่ ๒๐ กรกฎาคม 2562

เรื่อง แบบฟอร์มมาตรฐาน Clinical Trial Agreement ของมหาวิทยาลัยมหิดล

เรียน คณบดี/ผู้อำนวยการ

สิ่งที่ส่งมาด้วย แบบฟอร์มมาตรฐาน Clinical Trial Agreement

อ้างถึง ประกาศมหาวิทยาลัยมหิดล เรื่อง การดำเนินการศึกษาวิจัยทางคลินิก พ.ศ. 2561 ประกาศ ณ วันที่ 31 ตุลาคม พ.ศ. 2561 กำหนดให้การทำงานด้านการศึกษาวิจัยทางคลินิกที่ได้รับเงินสนับสนุนจากแหล่งทุนภายนอกทั้งในประเทศและต่างประเทศที่มหาวิทยาลัยหรือส่วนงานเป็นผู้รับผิดชอบดำเนินงาน เป็นการดำเนินการวิจัยภายใต้ข้อบังคับมหาวิทยาลัยมหิดลว่าด้วย การบริหารเงินอุดหนุนการวิจัย พ.ศ. 2560 และให้กองบริหารงานวิจัยเป็นหน่วยงานผู้รับผิดชอบ นั้น

ในการนี้ กองบริหารงานวิจัย มหาวิทยาลัยมหิดลจึงจัดทำแบบฟอร์ม Clinical Trial Agreement เพื่อเป็นแนวทางให้ทุกส่วนงานนำไปใช้ในการจัดทำสัญญารับทุน กรณีส่วนงาน/บริษัทคู่สัญญาไม่มีแบบฟอร์มสัญญาดังกล่าว รายละเอียดตามสิ่งที่ส่งมาด้วย โดยสามารถดาวน์โหลดแบบฟอร์มได้ที่เว็บไซต์กองบริหารงานวิจัย https://op.mahidol.ac.th/ra/orra_download/ ทั้งนี้ เมื่อจัดทำสัญญาแล้วขอให้ส่วนงานเสนอลงนาม โดยปฏิบัติตามคำสั่งมหาวิทยาลัยมหิดล ที่ 3337/2561 เรื่อง มอบอำนาจการดำเนินการศึกษาวิจัยทางคลินิก ลงวันที่ 13 พฤศจิกายน 2561

จึงเรียนมาเพื่อโปรดทราบและถือเป็นแนวปฏิบัติด้วย จักขอบพระคุณยิ่ง

(ศาสตราจารย์ นายแพทย์วัชร ชกขาร)

รักษาการแทนรองอธิการบดีฝ่ายวิจัยและวิชาการ

CLINICAL TRIAL AGREEMENT

The Clinical Trial Agreement ("**Agreement**") dated as of the date of last signature and effective as of the last signature date ("**Effective Date**") between the Parties

Parties

[Company/Institution Name], located at [insert Address] (the "**Sponsor**").
and

[Faculty Name], Mahidol University, located at [insert Faculty Address] (the "**Institution**").

1. SCOPE OF WORK

1.1 Principle Investigator. The Institution shall conduct and supervise the clinical trial in accordance with this Agreement through [Principle Investigator Name] (the "**Principle Investigator**"), who is an employee of the Institution.

The Institution and the Principle Investigator shall perform the clinical trial entitled [protocol title] (the "**Study**") as set forth in Protocol No. [protocol number] dated [date] which is attached hereto as Annex 1 in accordance with the Agreement and the Study.

1.2 Approvals. The Institution shall seek approval of the Study, the Protocol, and a written form of Informed Consent (as defined in Section 1.3) mutually acceptable to the Institution and the Sponsor, from the appropriate institutional review board (the "IRB"), and shall seek any other approvals required for the Study from applicable internal safety or review boards.

1.3 Informed Consent. The Institution shall obtain from each person participating in the Study a valid informed consent (the "Informed Consent"), signed by the Study (unless such signature is waived by the IRB) and appropriately documented. The Institution shall conduct the Study in a manner consistent with the Informed Consents and all other applicable consents.

1.4 Amendment of the Protocol. The Sponsor may amend the Protocol at any time. Any such amendment shall be in writing and sent to the Institution, and will not take effect until approved by the IRB. Following any such amendment to the Protocol, either Party may propose a related amendment to this Agreement (including the Payment Schedule, as defined in Section 11). The Parties shall negotiate in good faith with respect to any such proposed amendment. If the Parties are unable to agree upon such an amendment to this Agreement, either Party may terminate this Agreement pursuant to Article 12.

2. DURATION OF THE PROTOCOL AND NUMBER OF PARTICIPANT TO ENROLL

The study shall commence on [EC approval date]. The Institution and the Principle Investigator shall use its best efforts to complete the Study and to perform its obligations under the Agreement by [date].

The targeted number of participants to be enrolled into the Study (individually to be referred to as a "**Participant**" or collectively referred to as the "**Participants**") at [Faculty Name] which will be used by the Institution to conduct the Study is [number].

3. TERM OF AGREEMENT

3.1 The Agreement shall be effective from the Effective Date and shall cease upon completion of the Study as specified in the Study.

- 3.2 The following provisions shall survive termination or expiration of the Agreement: Section 6 (Confidential Information), Section 7 (Intellectual Property) and Section 8 (Publication), as well as any other provisions which by their terms are understood to survive termination or expiration of the Agreement.

4. STUDY DRUG/EQUIPMENT AND MATERIAL

- 4.1 The Sponsor shall use reasonable efforts to supply (or procure the supply), at no cost Institution, the quantities of the Study required to conduct the Study in accordance with the Protocol and applicable laws, regulations and guidelines, including in particular, but without limitation, GCPs.
- 4.2 The Institution shall, and will ensure that the Principle Investigator shall, ensure that the Study drug/Equipment is stored, dispensed and administered under proper conditions and in accordance with the Protocol, the Applicable Laws and, where relevant, the Sponsor's instructions.
- 4.3 The Study drug/Equipment must be used only for the purposed outlined the Protocol and the Institution shall not, and will ensure that the Principle Investigator shall not use, supply or otherwise make available any Study drug/Equipment for any others purposes, or engage in any promotion or commercialization of Study drug/Equipment for any unauthorized indication.
- 4.4 The Institution shall, and will ensure that the Principle Investigator shall, maintain complete and accurate records relating to the Study drug/Equipment consistent with the Protocol and as required by Applicable Laws. At the completion or termination of the Study or earlier termination of the Agreement all remaining Study shall, at the Sponsor's option, be returned to the Sponsor (at Sponsor's expense) or disposed of in accordance with Applicable laws.
- 4.5 The Sponsor will provide the Institution with the Materials required for the conduct of the Study. The Sponsor shall retain all rights, title and interest in and to the Materials unless otherwise agreed by the Sponsor in writing. The Materials may only be used by the Institution, the Principle Investigator and the [Faculty Name] staff to the extend required for the conduct of the Study.
- 4.6 The Institution shall be responsible for keeping any Materials in good repair and in such condition as they were on the date of delivery (fair wear and tear excepted). The Materials shall be kept and operated in a suitable environment and used only for the purpose for which they are intended, by trained staff in accordance with any instructions provided by the Sponsor.
- 4.7 The Institution shall comply with applicable law in the collection, storage, and transfer of any samples or other *human materials* taken from Study, and shall obtain any consents required from Study for the use of such materials in accordance with the Protocol. Any use of such human materials by a Party, whether in the Study or otherwise, shall be consistent with such consents and applicable law.

5. RECORDKEEPING AND REPORTING

- 5.1 The Institution and the Principle Investigator shall perform the following recordkeeping and reporting obligations in a timely fashion:
- a) preparing and maintaining complete and accurately written and electronic records including accounts, notes, reports, Case Report Forms, records of the Study Subject identifications, medical notes, clinical observations, laboratory tests and the receipt and disposition of the Study and all appropriate documentation and data for each Participant of the Study (the "**Records**")

- b) maintaining a copy of all Records for the longer of a) [number] years after the Study is completed or discontinued by Sponsor; or b) as required by the Applicable Laws;
- 5.2 The Principle Investigator shall ensure that it shall meet with representatives of Sponsor to discuss the progress of the Study and make notes and Case Report Forms for each Study Subject available for source data verification or auditing purposes by representatives of Sponsor or representatives and the officers of any authority.

On discovering any significant violations of the Study, the Principle Investigator shall notify Sponsor immediately.

6. CONFIDENTIAL INFORMATION

- 6.1 Subject to clause 6.2 and 6.3, each Party shall at all times keep confidential the Confidential Information. Each Party shall safeguard the other Party's Confidential Information with at least the same level of care as it affords to its own Confidential Information, and shall not use the other Party's Confidential Information for any purpose other than to perform its obligations under the Agreement. The Principle Investigator and all [Faculty Name] Staff shall be bound by obligations of confidentiality at least as restrictive as those obtained in the Agreement.
- 6.2 The obligations on each Party set out in Clause 6.1 shall survive for [Number] years after the expiry of termination of the Agreement, but shall not apply to any information which:
 - 6.2.1 was in that Party's possession (with full right to disclose) prior to receiving it from another Party, as demonstrated by written records;
 - 6.2.2 is public knowledge otherwise than as a result of any breach of this Clause or any similar Clause in any other relevant agreement; or
 - 6.2.3 it can demonstrate was developed independently without reference to the Confidential Information, or was received from a third party who has the right to disclose such information in a non-confidential manner.
- 6.3 A Party may disclose Confidential Information to the extent required by a court of competent jurisdiction, by a governmental, supervising or regulatory body, or otherwise in order to comply with Applicable Laws (including freedom of information legislation) provided always that (i) to the extent it is legally permitted to do so, the disclosing party gives the affected Party as much notice of such disclosure as possible; and (ii) the disclosing Party complies with the affected Party's reasonable directions for taking legally available steps to resist or narrow such requirement (at the affected Party's reasonable expense) and in any relevant restricts the disclosure to only those parts of the Confidential Information lawfully required to be disclosed.
- 6.4 The Parties acknowledge that damages alone would not be an adequate remedy for the breach of any of the terms of clause 6, and that in the event or threatened breach the Party that initially disclosed the Confidential Information shall be entitled to seek equitable relief and/or injunctive relief concerning any threatened or actual breach (in addition to any other rights and remedies it may have under the Agreement or otherwise)

7. INTELLECTUAL PROPERTY

- 7.1 All Intellectual Property created and provided by the Sponsor shall remain the sole property of the Sponsor.
- 7.2 The Principle Investigator shall promptly disclose and assign to the Sponsor all inventions and discoveries made by the Principle Investigator related to the Trial.

- 7.3 The Principle Investigator shall have a royalty-free right to use the results for non-commercial research and educational purposes.

8. PUBLICATION AND PUBLICITY

8.1 Publication

Sponsor may permit Institution and/or Principle Investigator to present the final results of the Study upon provision of at least 45 days written notice to Sponsor of all documents comprising the purposed publication or presentation. Sponsor shall not unreasonably withhold their consent to allow Institution and/or Principle Investigator to publish or present but may require reasonable amendments so that Confidential Information and/or Intellectual Property are not disclosed.

If the Study is a multi-center Study, then any publication or presentation by Institution and/or Principle Investigator may only occur together with the other sites in the Study.

8.2 Publicity

Institution agrees not to release any statement, information, advertisement, or publicity referring to Sponsor without the express written approval of Sponsor (if applicable).

9. INSURANCE AND INDEMNITY

- 9.1 Each Party shall ensure that adequate provision is made by way of insurance or indemnity arrangements sufficient to meet their obligations and liabilities under the Agreement and the Applicable Laws, in particular towards Subjects for personal injury arising as a result of participation in the Study.
- 9.2 The Sponsor agrees to indemnify the Institution against all direct costs, claims, liability, penalties or expenses (including reasonable legal fees and disbursements), (collectively "**Losses**") arising out of or relating to the conduct of the Study.
- 9.3 The Sponsor's indemnity under Clause 9.2 will not apply to the extent that such Losses arise from or relate to (a) any breach of the Agreement or Applicable Laws by the Institution and the Principle Investigator, or (b) any negligence, recklessness or willful act or omission by the Institution, the Principle Investigator or the [Faculty Name] Staff in the performance of their obligations under the Agreement.
- 9.4 If any third party makes a claim, or notifies an intention to make a claim, against the Institution which may reasonably be considered likely to give rise to a liability under this indemnity (a "**Claim**"), the Institution shall:
- 9.4.1 as soon as reasonably practicable, give written notice of the Claim to the Sponsor, specifying the nature of the Claim in reasonable detail;
 - 9.4.2 not make any admission of liability, agreement or compromise in relation to the Claim without the prior written consent of the Sponsor, such consent not to be unreasonably withheld; and
 - 9.4.3 take such action as the Sponsor may reasonably request to avoid, dispute, compromise or defend the Claim (including granting the Sponsor full conduct and control of the Claim).

10. COMPLIANCE, TRANSPARENCY, ANTI-CORRUPTION AND CONFLICT OF INTEREST

- 10.1 The Parties will ensure that neither they, nor any of their officers or employees, directly or indirectly offer, make, accept or request any Payments or Transfers of value to or from any official or other person, that is intended or could be seen, to influence any decision to obtain or retain business, to gain an improper advantage,

or to induce such official or other person to perform a function in violation of any statute, rule, or regulation, including but not limited to inducements, bribes, kickbacks and facilitation payments.

- 10.2 The Institution warrants that neither it nor any of its officers or employees (including the Principle Investigator and the [Faculty Name] staff) have engaged in any conduct that has resulted or may result in a criminal conviction, nor are currently excluded, debarred, suspended, or otherwise ineligible to participate in the Study and/or government health care programs in any country. The Institution agrees to notify the Sponsor immediately in the event it becomes aware that it or any of its officers or employees (including the Principle Investigator and the [Faculty Name] staff) are being investigated by any Regulatory Authority.
- 10.3 The Institution declares that neither the principle Investigator, nor any number of the [Faculty Name] Staff, is subject to any conflicting obligations or legal impediments and/or has any financial, contractual or other interests in the outcome of the Study that might interfere with the performance of the Study or that is likely to affect the reliability and robustness of the data generated in the Study. The Institution shall inform the Company immediately upon learning of the existence of any financial arrangement or interest between the Principle Investigator and the Sponsor.

11. PAYMENT

In consideration of the services rendered under the Agreement, the Sponsor shall pay the Institution in accordance with Annex 2.

12. TERMINATION

- 12.1 Either Party may terminate the Agreement for any safety and/or efficacy concerns or other ethical grounds by giving written notice to the other Party with immediately effect. In case of early termination, the Principle Investigator shall notify the relevant ethics committee of the early termination and Sponsor shall notify the regulatory authority and any other competent authorities within the timescales specified in the Study.
- 12.2 If Sponsor terminates the Agreement, Sponsor shall have no obligations under the Agreement except to reimburse the Institution for its reasonable costs and non-cancellable obligations incurred in the performance of the Study prior to receiving notice of termination.
- 12.4 The termination or expiry of this agreement shall not affect the rights and obligations of the Parties which accrued prior to the date of termination.

13. GENERAL

13.1 Notices

All notices, requests, demands, consents, approvals, offers or other communications given by a party under or in connection with the Agreement must be:

- (a) in writing;
 - (b) directed to the recipient's address
 - (c) hand delivered or sent by e-mail to that address;
- and such notices shall be addressed as follows:

To the Sponsor
Attention: [Insert Name]
Address: [Insert Address]
Email: [Insert Email]
Tel: [Insert telephone number]

To the Institution
Attention: [Insert Name]
Address: [Insert Address]
Email: [Insert Email]
Tel: [Insert telephone number]

with a copy to the Principal Investigator
[Principal Investigator Name]
Address: [Insert Address]
Email: [Insert Email]
Tel: [Insert telephone number]

13.2 Severability

The invalidity or unenforceability of any term or provision of the Agreement shall not affect the validity or enforceability of any other term or provision hereof.

13.3 Assignment

- 13.3.1 The Agreement shall not be assigned by either party, in whole in part, without the prior written consent of the Parties hereto.
- 13.3.2 Sponsor shall have the right at any time to assign or transfer any or all of its rights and obligations under the Agreement to any of its Affiliates. For the purpose of the Agreement **"Affiliate"** means any corporation, company, partnership, joint venture or other entity which controls, is Controlled by, or is under common Control with a person or entity. **"Control"** means the ownership of more than fifty percent (50%) of the issued share capital or the legal power to direct or cause the direction of the general management and policies of/the party in question.

13.4 Subcontracting

The Institution shall not retain any subcontractor to perform any of its obligations under this Agreement without the prior written consent of Sponsor. Any such consent shall not relieve the Institution of its obligations hereunder.

13.5 Governing law and dispute resolution

This Agreement shall be governed by and construed in accordance with the laws of Thailand. Any dispute, controversy or claim arising out of, or in connection herewith, including without limitation, its formation, validity, interpretation, performance, breach or termination, as well as non-contractual claims shall be amicably resolved through negotiations between the parties.

The competent court of Thailand shall have exclusive jurisdiction over any dispute arising out of this Agreement, which cannot solve amicably between the parties.

13.6 Entire Agreement

The Agreement together with the Appendices (all of which are incorporated by reference) constitutes the entire agreement between the Parties with respect to the subject matter of the Agreement and supersedes all prior agreements, whether written or oral, with respect to that subject matter.

13.7 Language

All reports, correspondences, notices, markings, drawings and other communications shall be in English language. The English version of this Agreement shall prevail.

IN WITNESS WHEREOF, the parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives.

Sponsor:

Signature:

Printed Name:

Title:

Date:.....

Faculty of.....MAHIDOL UNIVERSITY

Signature:

Printed Name:

Title:

Date:.....

Acknowledge by the Principle Investigator:

Signature:

Printed Name:

Title:

Date:.....

Annex 1 Study Protocol

Annex 2 Payment

A. Payment Schedule

Activity	Payment per Participant
Total per subject	
20% overhead	

B. Payment Accounts

For Ethics Committee

Account Name:

Account no.:

Bank Name:

Branch:

Bank Address:

For other payments including overhead

Account Name: Mahidol University

Account no.: 3164038367

Bank Name: The Siam Commercial Bank Public Company Limited

Branch: Salaya Branch

Bank Address: 28 Phutthamonthon 4 Rd., Salaya, Phutthamonthon, Nakhon Pathom
73170 THAILAND

SWIFT Code: SICOTHBK

C. The Institution shall send the invoices to:

[Sponsor Name]

[Sponsor Address]

Annex 3 Equipment

[illegible]