

正本

檔 號：
保存年限：

衛生福利部食品藥物管理署 函

機關地址：11561 臺北市南港區昆陽街161-2號

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受文者：中華民國西藥代理商業同業公會

發文日期：中華民國102年11月27日

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速別：

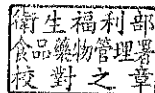
密等及解密條件或保密期限：

附件：藥品臨床試驗合約內容參考範本1份

主旨：有關衛生福利部委託財團法人醫藥品查驗中心研擬之
「藥品臨床試驗合約內容參考範本」(如附件)，業已完成
並建置於該中心網站 (<http://www2.cde.org.tw>) 供各界參
考，請 查照並轉知所屬。

正本：中華民國西藥代理商業同業公會、中華民國西藥商業同業公會全國聯合會、中
華民國開發性製藥研究協會、中華民國製藥發展協會、中華民國學名藥協會、
中華民國藥品行銷暨管理協會、台北市西藥代理商業同業公會、臺灣區製藥工
業同業公會、台灣研發型生技新藥發展協會

副本：財團法人醫藥品查驗中心



署長葉明功

本案依分層負責規定
授權組室主管決行

藥品臨床試驗合約內容參考範本

檢核表

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5. Protocol			
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12. Adverse Event Reporting			
13. Investigational Drug			
14. Study Data, Biological Samples, and Study Records			
15. Monitoring, Inspections, and Audits			
16. Publications			
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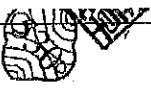


18.	Termination			
19.	Use of Name			
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ARTICLE	REFERENCE CLAUSES	ANNOTATION
Cover Page	<p> CLINICAL TRIAL AGREEMENT between Dr. [Insert Investigator's name] [Insert Investigator's address] hereinafter referred to as the "Investigator," and [Insert Institution's name] [Insert Institution's address] hereinafter referred to as the "Institution," and [Insert Sponsor's name], trading as [Insert Sponsor's name abbreviation] [Insert Sponsor's address] hereinafter referred to as [Insert Sponsor's name abbreviation] Protocol number [Insert Protocol number] </p>	




<p>Preamble</p> <p><u>Insert Name and Address ("SPONSOR")</u> desires to retain <u>Insert Institution Name and Address</u> ("Institution") to conduct a clinical study (the "Study") in relation to <u>Insert Product Name</u> (the "Investigational Drug(s)") effective as of the date this Clinical Study Agreement (the "Agreement") is fully executed (the "Effective Date"). In consideration of the mutual promises set forth herein, the parties agree as follows:</p>	<p>1. Preamble is to identify and define the parties and the nature of the agreement.</p>
<p>1. RESPONSIBILITY OF INVESTIGATORS AND RESEARCH STAFF</p> <p>1.1 Principal Investigator. The Study will be conducted by <u>Insert Institution Name</u> (Principal Investigator). Institution agrees to notify Sponsor as soon as practicable if Investigator will be leaving the Institution or is otherwise no longer able to perform the Study. The appointment of a new Investigator must have the prior approval of Sponsor.</p> <p>1.2 Subinvestigators and Research Staff. Principal Investigator and Institution will ensure that only individuals who are appropriately trained and qualified assist in the conduct of the Study as subinvestigators or research staff.</p> <p>1.3 Compliance Obligations. Principal Investigator and Institution are responsible for compliance by all Study personnel with the terms of this Agreement, International Conference on Harmonization Good Clinical Practice (ICH GCP) guidelines, the Good Clinical Practice of Taiwan ("Taiwan GCP"), and applicable law, regulation and guidance. Principal Investigator will have overall responsibility for the conduct of the Study, including all those responsibilities assigned to principal investigators by the relevant regulations governing the conduct of clinical investigations. Institution will provide appropriate oversight of Principal Investigator's activities within the Institution.</p>	<p>1. The investigator(s) should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory requirement(s), and should provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB/IEC, and/or the regulatory authority (ies). (ICH B6 4.1.1)</p> <p>2. The investigator should be thoroughly familiar with the appropriate use of the investigational product(s), as</p>



	<p>1.4 Debarment. The Institution and the Investigator hereby represent and warrant that neither of them have been debarred or disqualified from carrying out clinical studies nor have any of the individuals involved in the administration of the services for the Trial. If the Institution or the Investigator became aware of the debarment or disqualification, they will immediately notify Sponsor.</p>	<p>described in the protocol, in the current Investigator's Brochure, in the product information and in other information sources provided by the sponsor. (ICH E6 4.1.2)</p> <p>3. The investigator should be aware of, and should comply with, GCP and the applicable regulatory requirements. (ICH E6 4.1.3)</p> <p>4. The investigator/institution should permit monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authority (ies). (ICH E6 4.1.4)</p> <p>5. The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.</p>
<p>2</p>	<p>2. RESPONSIBILITY OF SPONSOR</p> <p>SPONSOR is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs to ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s).</p>	<p>1. The sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs to ensure that trials are conducted</p>




3	<p>3. COMMENCEMENT AND DURATION</p> <p>3.1 Subject Enrollment. Institution and Investigator have agreed to enroll Study Subjects (defined below) by [REDACTED] unless Sponsor modifies the enrollment period by written notification. A Study Subject is one who meets all Protocol criteria for inclusion in the Study ("Study Subject(s)").</p> <p>3.2 Multi-Center Studies. Institution and Investigator have been made aware of that this is a multi-center Study and therefore a competitive recruitment situation shall apply. Sponsor may end Study Subject enrollment early if the total enrollment needed for a multi-center study has been achieved before the end of the enrollment period for this Study.</p>	<p>and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s). (ICH E6 5.1.1)</p> <p>1. To better identify the starting time, end time, numbers of patient to be recruited for the study.</p>
5	<p>4. FUNDING</p> <p>SPONSOR will provide funding to the Institution for the Study as delineated in Attachment A (the "Budget") and subject to the terms specified in this Agreement.</p> <p>5. PROTOCOL</p>	<p>1. The financial aspects of the trial should be documented in an agreement between the sponsor and the investigator/institution. (ICH E6 5.9)</p> <p>1. The contents of a trial protocol should generally include the</p>

	<p>5.1 Principal Investigator will conduct the Study and Principal Investigator and Institution will perform all Study-related activities in accordance with the Protocol, including but not limited to obtaining Institutional Review Board/ Independent-Ethics Committee ("IRB/IEC") approval, adverse event reporting, and publications of Study results, as set out in the Protocol and this Agreement.</p> <p>5.2 Amendments. The Protocol may be modified only by a written amendment, signed by both SPONSOR and the Principal Investigator and approved by the responsible IRB/IEC ("Amendment"), except for emergency changes necessary to protect the safety of individuals who are enrolled into the Study in accordance with the Protocol conditions ("Study Subjects), as described in the Protocol.</p> <p>5.3 No Additional Research. No additional research may be conducted on Study Subjects during the conduct of the Study or on biological samples collected during the conduct of the Study unless it is approved by SPONSOR and the responsible IRB/IEC and documented as an Amendment to the Protocol or made subject to mutually agreeable terms otherwise documented by the parties.</p>	<p>following topics: General information, Background information, Trial objective and purpose, Trial design, Selection and withdrawal of subjects, Treatment of subjects, Assessment of efficacy, Assessment of safety, Statistics, Direct access to source data/documents, Quality control and quality assurance, Ethics, Data handling and record keeping, Financing and insurance, Publication policy, and Supplements. (ICH E6 6)</p>
<p>6</p>	<p>6. STUDY CONDUCT</p> <p>6.1 Charging Study Subjects. Neither Principal Investigator nor Institution will charge a Study Subject or third-party payer for Investigational Drug or for any services reimbursed by SPONSOR under this Agreement.</p> <p>6.2 Safety Measures and Serious Breaches. Principal Investigator and/or Institution will</p>	<p>1. Systems with procedures that assure the quality of every aspect of the trial should be implemented. (ICH E6 2.13)</p>





	<p>inform SPONSOR immediately of (a) any urgent safety measures taken to protect Study Subjects against immediate hazard and (b) any serious breaches of the Protocol, Taiwan GCP or ICH GCP guidelines of which Principal Investigator or Institution become aware.</p>	
7	<p>7. INDEPENDENT ETHICS COMMITTEE OR INSTITUTIONAL REVIEW BOARD</p> <p>A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favorable opinion.</p>	<p>1. A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favorable opinion. (ICH E6 2.6)</p>
8	<p>8. CONFIDENTIALITY</p> <p>8.1 Confidentiality Neither the Institution nor the Investigator (nor any of their employees, directors, officers or agents, sub-investigators or research staff) shall disclose to any third party or use for any purpose other than for the performance of the Trial any data, records or other information disclosed to Institution or Investigator by SPONSOR or generated as a result of this Trial (hereinafter, collectively "Confidential Information") without the prior written consent of Sponsor. Such Confidential Information shall remain the confidential and proprietary property of Sponsor and shall be disclosed by Institution and Investigator only to their employees or agents, including sub-investigators and research staff, who "need to know" and who have agreed to terms of confidentiality substantially similar to those terms contained herein. The obligation of nondisclosure shall not apply to the following Confidential Information:</p> <p>a. Confidential Information that is or becomes publicly available through no fault of Institution</p>	<p>1.</p>



	<p>and Investigator;</p> <p>b. Confidential Information that is disclosed to Institution and Investigator by a third party legally entitled to disclose such Confidential Information;</p> <p>c. Confidential Information that is already known to Institution and Investigator as shown by their prior written records; and</p> <p>d. Confidential Information disclosed to a government authority or by order of a Court of competent jurisdiction.</p> <p>8.2 All Confidential Information containing personal data shall be handled in accordance with all applicable laws, including without limitation laws relating to the protection of intellectual property and confidential information.</p> <p>8.3 The confidential obligations will survive the termination of this Agreement.</p>	
<p>9</p>	<p>9. INTELLECTUAL PROPERTY</p> <p>Any inventions or discoveries (whether patentable or not), innovations, suggestions, ideas, reports or other intellectual property made or developed by Institution or Investigator in connection with this Trial shall become the sole and exclusive property of SPONSOR. Upon SPONSOR's request and at SPONSOR's expense, Institution and Investigator shall take such actions as SPONSOR deems necessary or appropriate to obtain patent or other proprietary protection in Sponsor's name with respect to any of the foregoing. The Institution and the Investigator agree that CRFs, the final report and other results of the Study, if any, together with any patents, patent applications, inventions, discoveries, modifications and other like forms of</p>	<p>1.</p>



	<p>protection, and other intellectual property rights and other information not in the public domain which may subsist in any part of the world ("Intellectual Property") shall also be owned by SPONSOR.</p>	
10	<p>10. DATA PROTECTION AND FINANCIAL DISCLOSURE</p> <p>10.1 Personal Data. Personal data is any information from which it is possible to identify an individual including, without limitation, Study Subjects. Personal data which concerns health information is sensitive personal data. Personal data collected in the Study shall include personal data relating to the Principal Investigator, research staff, third parties and possibly Study Subjects (including sensitive personal data relating to Study Subjects) (collectively "Personal Data") which may be subject to specific legislation relating to the processing, storage, transfer and use of such data. Principal Investigator and Institution will comply with all relevant laws relating to the protection and use of Personal Data and data privacy in its conduct and reporting of the Study. Principal Investigator and Institution will take all technical and organizational measures to prevent unauthorized or unlawful processing or accidental loss or destruction of, or damage to, or disclosure of such data. SPONSOR will take appropriate measures to protect the confidentiality and security of all Personal Data that it receives in connection with the Study. SPONSOR may disclose Personal Data of Principal Investigator and research staff if prior written consent has been obtained from the relevant personnel.</p> <p>10.2 Use by SPONSOR. Personal Data will be processed and used for the purposes of administration of this Agreement and in connection with the Study. Information relating to the Principal Investigator, research staff and sub-investigators will be held on one or more databases</p>	<p>1. The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s). (ICH E6 2.11)</p>

	<p>for the purposes of determining their involvement in future research and in order to comply with any regulatory requirements.</p> <p>10.3 Financial Disclosure. Where the Study is deemed by SPONSOR to be a "covered study" for the purpose of the United States Food and Drug Administration regulation entitled "Financial Disclosure by Clinical Investigators" (the "FDA Regulation"), Principal Investigator agrees, and Principal Investigator and Institution will ensure that any co-investigator or sub-investigator engaged in the Study agrees, to disclose to SPONSOR all relevant financial and other information (including details of equity interests in SPONSOR or any of its affiliates) relating to the Principal Investigator, co-investigator or sub-investigators, as the case may be (and, where relevant, spouse and dependants of Principal Investigator, co-investigator and/or sub-investigator) as required by SPONSOR in order to comply with the FDA Regulation.</p>	
<p>11</p>	<p>11. INFORMED CONSENT AND SUBJECT RECRUITMENT</p> <p>11.1 Informed Consent. Principal Investigator will obtain a written informed consent from each Study Subject and will maintain a signed original of that consent in that Study Subject's record. SPONSOR will provide a template informed consent document for the Study. Principal Investigator and Institution must not make any changes to this document without the prior written approval of the SPONSOR and the responsible IRB/IEC (including any revisions made during the course of the Study), such approval to be obtained before the revised informed consent document is used.</p> <p>11.2 Subject Recruitment. Principal Investigator and Institution will provide SPONSOR an</p>	<p>1. Freely given informed consent should be obtained from every subject prior to clinical trial participation. (ICH E6 2.9)</p>

<p>opportunity to review and approve the content of any Study recruitment materials directed to potential Study Subjects before such materials are used. This requirement applies to all such materials, regardless of medium.</p>	
<p>12. ADVERSE EVENT REPORTING</p> <p>12.1 Within 24 hours of first knowledge of any SAE, Institution and Principal Investigator must notify SPONSOR. This applies also for any event that could affect the safety of the trial participants or the conduct of the trial.</p> <p>12.2 The relevant information should be completed on the "adverse event form". The form must be completed and forwarded to SPONSOR immediately. The Institution and Principal Investigator shall promptly provide SPONSOR any and all information and assistance for SPONSOR to process filing with and report to the competent authority in Taiwan and to comply with the requirement of the Ministry of Health and Welfare and all laws and regulations in Taiwan in connection with any AE or SAE under the Trial.</p>	<p>1. All serious adverse events (SAEs) should be reported immediately to the sponsor except for those SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. (ICH E6 4.11.1)</p> <p>2. Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol (ICH E6 4.11.2)</p> <p>3. The sponsor should expedite the reporting to all concerned investigator(s)/institutions(s), to the IRB(s)/IEC(s), where required, and to the regulatory authority (ies) of</p>


13	<p>13. INVESTIGATIONAL DRUGS</p> <p>13.1 SPONSOR will provide Institution, at no charge, with sufficient quantities of the Investigational drug that is being studied ("Investigational Drug") to conduct the Study. Unless otherwise indicated in Agreement, SPONSOR will also provide at no charge, or cover the costs of, any other Protocol-required drugs (e.g., placebo, comparator drug, concomitant drug). Any other Protocol-required product that SPONSOR provides or covers the cost of is, together with the Investigational Drug, considered "Investigational Product."</p> <p>13.2 Custody and Dispensing. Principal Investigator and Institution will maintain appropriate control of supplies of Investigational Product and will not administer or dispense it to anyone who is not a Study Subject, or provide access to it to anyone except Study personnel. Principal Investigator and Institution will store Investigational Product as specified by SPONSOR and according to applicable regulatory requirements.</p> <p>13.3 Use. Principal Investigator and Institution will use Investigational Product only as specified in the Protocol. Any other use of Investigational Product constitutes a material breach of this Agreement.</p> <p>13.4 Ownership of Investigational Drug. Investigational Drug is and remains the property of SPONSOR. Except for, and limited to, the use specified in the Protocol, SPONSOR grants</p>	all adverse drug reactions (ADRs) that are both serious and unexpected. (ICH E6 5.17.1)
		<p>1. Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol. (ICH E6 2.12)</p>

	<p>Principal Investigator and Institution no express or implied intellectual property rights in the Investigational Drug or in any methods of making or using the Investigational Drug.</p>	
14	<p>14. STUDY DATA, BIOLOGICAL SAMPLES, AND STUDY RECORDS</p> <p>14.1 Study Data. During the course of the Study, Principal Investigator will collect certain data as specified in the Protocol and submit it to SPONSOR, SPONSOR's agent, or representative ("Study Data"). Principal Investigator will ensure accurate and timely collection, recording, and submission of Study Data, including adhering to timelines for data entry set out in the CRF Completion Requirements document or other data entry requirements document provided to Institution by SPONSOR.</p> <p>a. Ownership of Study Data. Subject to Principal Investigator's right to use the Study Data to publish the results of the Study in accordance with Section 16 of this Agreement (Publications), SPONSOR is the exclusive owner of all Study Data.</p> <p>b. Medical Records. Study Subject-related medical records that are not submitted to SPONSOR may include some of the same information as is included in Study Data; however, SPONSOR makes no claim of ownership to those documents or the information they contain.</p> <p>c. Data Review. SPONSOR will review the Study Data it receives on an ongoing basis. SPONSOR will comply with applicable regulations or local laws requiring notification of participating investigators of new safety information about the SPONSOR Drug. SPONSOR will notify Principal Investigator and Institution of any other new information of which SPONSOR becomes aware that could affect the safety of the subjects or influence the conduct of</p>	<p>1. All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification (ICH E6 2.10)</p>



the Study.

- d. **Study Results.** After analysis of Study Data from all sites is complete, SPONSOR will provide Principal Investigator and Institution with a summary of the overall results of the Study. If the results show that Study Subject safety could be adversely affected, SPONSOR, in consultation with the IRB/IEC as appropriate, will cooperate with Principal Investigator and Institution to ensure that those results are appropriately communicated to the subjects by Principal Investigator and/or Institution during the 2 year period following the close of the Study.
- 14.2 **Biological Samples.** If so specified in the Protocol and the informed consent document, Principal Investigator may collect and provide to SPONSOR or SPONSOR's designee the biological samples (e.g., blood, urine, tissue, saliva, etc.) obtained from Study Subjects for testing that is not directly related to subject care or safety monitoring, such as pharmacokinetic, pharmacogenomic, or biomarker testing ("Biological Samples").
- a. **Use.** Principal Investigator and Institution will not use Biological Samples collected under the Protocol in any manner or for any purpose other than that described in the Protocol. SPONSOR will use Biological Samples only in ways permitted by the informed consent document under which they were obtained.
- b. **Analysis Data.** SPONSOR or SPONSOR's designees will test Biological Samples as described in the Protocol. If SPONSOR provides Biological Sample Analysis Data to Principal Investigator or Institution, that data will be subject to the permitted use provisions of Section 14.1 (Study Data) of this Agreement and Section 16 (Publications) considered part of Study Data

	<p>for purposes of this Agreement and may be used by Principal Investigator to prepare publications of the results of the Study (see Section 13, Publications).</p> <p>c. Ownership. SPONSOR is the exclusive owner of all Biological Sample Analysis Data.</p> <p>14.3 Study Records. Institution will retain each Study Subject's Study records, which include the Principal Investigator's copies of all Study Data as well as relevant source documents (collectively, "Study Records"), under storage conditions conducive to their stability and protection, for a period of fifteen (15) years after termination of the Study unless SPONSOR authorizes, in writing, earlier destruction. Principal Investigator and Institution agree to contract SPONSOR prior to destroying any records and further agree to permit SPONSOR to ensure that the records are retained for a longer period if necessary, at SPONSOR's expense, under an arrangement that protects the confidentiality of the records (e.g., secure off-site storage).</p> <p>15. MONITORING, INSPECTIONS, AND AUDITS</p> <p>15.1 Monitoring. SPONSOR will monitor the Study. In addition, SPONSOR or an external service provider acting on its behalf is entitled at its absolute discretion (and in such form as SPONSOR sees fit) to monitor and audit the conduct of the Study. Upon reasonable notice and during regular business hours, Principal Investigator will make himself/herself and any other investigators or research staff working under his/her direction and control available to SPONSOR representatives as required to allow SPONSOR to monitor Study conduct. Upon reasonable notice and during regular business hours, Institution will permit SPONSOR representatives access to the premises, facilities, Study Records, and any investigators and research staff who are Institution employees or contractors as required to monitor Study conduct.</p>	<p>1. The sponsor should ensure that the trials are adequately monitored. The sponsor should determine the appropriate extent and nature of monitoring. (ICH E6 5.18.3)</p>
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SPONSOR will promptly notify Principal Investigator of any monitoring findings that could affect the safety of subjects or influence the conduct of the Study. Principal Investigator will inform Institution and Study Subjects of such findings as appropriate.

15.2 Inspections and Audits. Principal Investigator and Institution acknowledge that the Study is subject to inspection by regulatory agencies worldwide and that such inspections may occur after completion of the Study and may include auditing of Study Records. SPONSOR may also audit Study Records during or after the Study as part of its monitoring of Study conduct.

a. Notification. Principal Investigator will notify SPONSOR as soon as reasonably possible if the site is inspected or scheduled to be inspected by a regulatory agency in relation to the Study.

b. Right to be Present. If not prohibited by law, SPONSOR will have the right to be present during, and participate in, any such inspection, audit, investigation, or regulatory action.

c. Cooperation. Principal Investigator and Institution will cooperate with regulatory agency or SPONSOR representatives in the conduct of inspections and audits and will ensure that Study Records are maintained in a way that facilitates such activities.

d. Resolution of Discrepancies. Principal Investigator will promptly resolve any discrepancies that are identified between the Study Data and the subject's medical records.

e. Inspection Findings and Responses. Principal Investigator or Institution will promptly

forward to SPONSOR copies of any inspection findings that Principal Investigator or Institution receives from a regulatory agency in relation to the Study. Whenever feasible, Principal Investigator and Institution will also provide SPONSOR with an opportunity to prospectively review and comment on their responses to such regulatory agency inspections in regard to the Study or information from a regulatory agency that could have an impact on the Study.

16. PUBLICATIONS

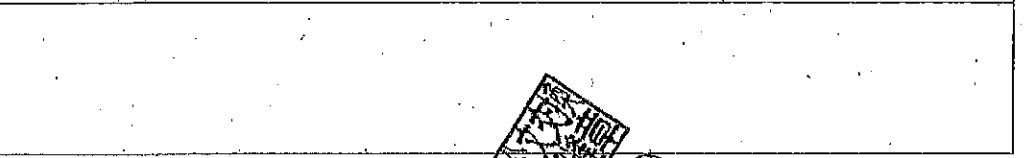
Notwithstanding the obligations of Confidentiality set forth above, Institution and/or Investigator will be free to publish and present the results of the Study subject to the following conditions: Institution and/or Investigator will provide Sponsor with a copy of any proposed publication or presentation for review and comment at least forty-five (45) days prior to such presentation or submission for publication. At the expiration of such forty-five (45) day period, Institution and/or Investigator may proceed with the presentation or submission for publication unless Sponsor has notified Institution and/or Investigator in writing that such proposed publication and/or presentation discloses Sponsor's confidential and proprietary technical information. Sponsor shall inform Institution and/or Investigator in writing of any changes or deletions in such presentation or publication necessary to protect Sponsor's confidential and proprietary technical information and Institution and Investigator hereby agree to make any such changes or deletions prior to publication. Further, upon the request of Sponsor, Institution and Investigator will delay publication or presentation for up to ninety (90) days to permit Sponsor to take necessary actions to protect its intellectual property interests.


To the extent that the Institution's participation in the Protocol is a part of a multi-center study,

1. Institution may freely publish and disseminate the results of their investigative findings hereunder and shall solely determine the authorship and contents of any such paper.
2. Institution shall provide sponsor with a copy of the papers (manuscript, poster abstract, lecture or oral presentation) at least (30-60) days prior to their submission to a scientific journal or presentation at scientific meetings.
3. Sponsor may comment upon, but may not make any editorial changes to, the results and conclusions set forth in the papers; however, if identified by sponsor, any Sponsor

<p>17</p>	<p>Institution and Principal Investigator agree that an initial Public Presentation of their results shall occur only together with the other sites unless specific written permission is obtained in advance from Sponsor for Public Presentation of separate results. Sponsor shall advise as to the implications of timing of any Public Presentation in the event clinical trials are still in progress at sites other than the Institution's and any institution participating in a multi-center study shall follow the Public Presentation review procedures set forth in this Article. Institution and Principal Investigator may publish their results in accordance with this Agreement if a joint publication is not completed within twelve (12) months after completion of the Study at all Study sites and locking of the database.</p>	<p>Confidential Information that may be contained therein shall be deleted.</p> <p>4. If Study is part of a multi-center trial, Institution agrees that the first publication is to be a joint publication covering all centers. However, if a joint manuscript has not been submitted for publication within 12 months of completion or termination of Study at all participating sites, Institution is free to publish separately.</p>
<p>17. INDEMNIFICATION</p> <p>17.1 SPONSOR indemnifies and holds harmless the Investigator and Institution and their employees and agents, including sub-investigators and research staff, against all claims and proceedings (to include any settlements or ex-gratia payments made with the consent of the parties hereto and reasonable legal and expert costs and expenses) made or brought (whether successfully or otherwise) by or on behalf of Subjects taking part in the Study (or their dependants) against the Investigator or Institution or any of their employees or agents, including sub-investigators and research staff, for personal injury (including death) to Subjects arising out of or relating to the administration of the Investigational Product under investigation or any clinical intervention or procedure provided for or required by the Protocol to which the Subjects</p>	<p>1. If required by the applicable regulatory requirement(s), the sponsor should provide insurance or should indemnify (legal and financial coverage) the investigator/the institution against claims arising from the trial, except for claims that arise from malpractice and/or negligence. (ICH E6 5.8.1)</p> <p>2. The sponsor's policies and</p>	<p>1. If required by the applicable regulatory requirement(s), the sponsor should provide insurance or should indemnify (legal and financial coverage) the investigator/the institution against claims arising from the trial, except for claims that arise from malpractice and/or negligence. (ICH E6 5.8.1)</p> <p>2. The sponsor's policies and</p>

<p>would not have been exposed but for their participation in the Study.</p>	<p>17.2 The above indemnity by SPONSOR shall not apply to any such claim or proceeding:</p> <p>(a) to the extent that such personal injury (including death) is caused by the negligent or wrongful acts or omissions or breach of statutory duty of the Investigator, Institution, or their employees or agents, including sub-investigators and research staff;</p> <p>(b) to the extent that such personal injury (including death) is caused by the failure of the Investigator, Institution, or their employees or agents, including sub-investigators and research staff, to conduct the Study in accordance with the Protocol;</p> <p>17.3 SPONSOR shall keep the Investigator and/or Institution and its legal advisers fully informed of the progress of any such claim or proceeding, will consult fully with the Institution on the nature of any defence to be advanced and will not settle any such claim or proceeding without the written approval of the Investigator and/or Institution (such approval not to be unreasonably withheld).</p> <p>17.4 Institution and Investigator warrant that they will be liable for their medical malpractice and negligence in the participation in, and conducting of, the Trial, and will obtain and maintain adequate means and resources, as required in accordance with local laws and regulations.</p>	<p>procedures should address the costs of treatment of trial subjects in the event of trial-related injuries in accordance with the applicable regulatory requirement(s). (ICH E6 5.8.2)</p> <p>3. When trial subjects receive compensation, the method and manner of compensation should comply with applicable regulatory requirement(s). (ICH E6 5.8.3)</p>
<p>18</p>	<p>18. TERMINATION</p> <p>18.1 Termination Events. Termination of this Agreement will be triggered by the earlier of any of the following events.</p>	<p>1. If the trial is prematurely terminated or suspended for any reason, the investigator/institution should promptly inform the trial subjects,</p>


	<p>a. Disapproval by IRB/IEC. If the Study cannot be initiated because of IRB/IEC's disapproval, this Agreement will terminate immediately.</p> <p>b. Study Completion. This Agreement will terminate when the Study is complete, which means the conclusion of all Protocol-required activities for all enrolled subjects.</p> <p>c. Early Termination of Study. This Agreement will terminate if the Study is terminated early as described below.</p> <p>(1) Termination of Study Upon Notice. SPONSOR may terminate the Study for any reason upon 30 days' written notice to Institution.</p> <p>(2) Immediate Termination of Study by SPONSOR. SPONSOR may terminate the Study immediately upon written notice to Institution for causes that include failure to enroll subjects at a rate sufficient to achieve Study performance goals; material unauthorized deviations from the Protocol or reporting requirements; circumstances that in SPONSOR's opinion pose risks to the health or well-being of Study Subjects; or regulatory agency actions relating to the Study or the Investigational Drug; or any non-compliance by the Institution or Principal Investigator with the terms of local laws or non-compliance with the terms of Anti-Bribery and Anti-Corruption including in circumstances where SPONSOR becomes aware (a) that improper payments are being or have been made to Government Officials or any other person by the Institution, Principal Investigator or those acting on behalf of the Institution or Principal Investigator with respect to services performed on behalf of SPONSOR, or (b) that the Institution, Principal Investigator or those acting on behalf of the Institution or Principal Investigator with respect to services performed on behalf of SPONSOR has accepted any payment, item, or benefit, regardless of value, as an improper inducement to award, obtain or retain business or otherwise gain or grant an improper business advantage from or to any other person or entity.</p> <p>(3) Immediate Termination of Study by Principal Investigator or Institution. Principal</p>	<p>should assure appropriate therapy and follow-up for the subjects, and, where required by the applicable regulatory requirement(s), should inform the regulatory authority (ies). (ICH E6 4.1.2)</p> <p>2. If a trial is prematurely terminated or suspended, the sponsor should promptly inform the investigators/institutions, and the regulatory authority (ies) of the termination or suspension and the reason(s) for the termination or suspension. The IRB/IEC should also be informed promptly and provided the reason(s) for the termination or suspension by the sponsor or by the investigator/institution, as specified by the applicable regulatory requirement(s). (ICH E6 5.2.1)</p>
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Investigator or Institution may terminate the Study immediately upon notification to SPONSOR if requested to do so by the responsible IRB/IEC or if such termination is required to protect the health of Study Subjects.


18.2 Payment upon Early Termination. If the Study is terminated early, SPONSOR will pay for work already performed, in accordance with Attachment A, less payments already made for such work. SPONSOR will also cover any non-cancelable expenses, other than future personnel costs, so long as they were properly incurred and prospectively approved by SPONSOR and only to the extent they cannot reasonably be mitigated. If the Study cannot be initiated because of disapproval by the IRB/IEC and through no fault of Institution, SPONSOR will reimburse Institution for IRB/IEC fees and for any other expenses that were prospectively approved, in writing, by SPONSOR. Notwithstanding the above, the Institution and Principal Investigator shall be liable for damages or remedies as provided by law and will not be entitled to any further payment if the Agreement is terminated early pursuant to section 16.1 c(2) for non-compliance with the terms of Anti-Bribery and Anti-Corruption of this Agreement, regardless of any activities undertaken by the Institution or Principal Investigator or agreements with third parties entered into prior to termination which concern the Study and the Institution and/or Principal Investigator is responsible for any obligations under such agreements with third parties.

18.3 Return of Materials. Unless SPONSOR instructs otherwise in writing, upon termination of the Agreement, Principal Investigator and Institution will promptly return, in accordance with SPONSOR instructions, all materials supplied by SPONSOR for Study conduct, including unused Investigational Drug, unused Case Report Forms, and any SPONSOR-supplied Equipment and Materials.





19	<p>19. USE OF NAME</p> <p>No party will use the name of any other party, or any of its employees, for promotional or advertising purposes without written permission from the party to be named.</p>	<p>1. No party shall use the name of any other party, or any of its employees, for promotional or advertising purposes without written permission from the other party.</p>
20	<p>20. INDEPENDENT CONTRACTOR</p> <p>The Investigator/Institution and their staff are acting as independent contractors of SPONSOR and shall not be considered the employees or agents of SPONSOR. SPONSOR shall not be responsible for any employee benefits, pensions, workers' compensation, withholding, or employment-related taxes as to the Investigator/Institution or their staff.</p>	<p>1. The Investigator/Institution and their staff are acting as independent contractors of SPONSOR and shall not be considered the employees or agents of SPONSOR.</p>
21	<p>21. ANTI-CORRUPTION</p> <p>a. Institution and Investigator represent and warrant that neither they nor any individual or entity acting on their behalf, nor any payee under this Agreement, will, directly or indirectly, offer or pay, or authorize an offer or payment of, any money or anything of value to any Public Official (defined below) or public entity, with the knowledge or intent that the payment, promise or gift, in whole or in part, will be made in order to influence an official act or decision that will assist SPONSOR or the Institution in securing an improper advantage or in obtaining or retaining business or in directing business to any person or entity.</p> <p>b. Institution and Investigator represent and warrant that neither they, nor any payee under this Agreement, nor any person or entity acting on their behalf is a Public Official with the ability to influence an official act. Institution will notify SPONSOR in writing if Investigator a payee or</p>	<p>1.</p>

	<p>any person or entity acting on Institution's behalf becomes a Public Official with the ability to influence an official act during the term of this Agreement.</p> <p>c. Without prejudice, and in addition to the above, Institution and Investigator hereby represents, warrants and undertakes that neither Institution nor Investigator nor any of their employees or agents has ever or will ever offer, promise or give a bribe (in any form, including without limitation payments, gifts or other benefits) directly or indirectly via an intermediary or agent to any public official (including without limitation an official or agent of any pharmaceutical regulatory authority, other governmental authority or public international organisation) or other third party or otherwise for the purpose of securing an improper advantage, obtaining or retaining business or a business advantage or the improper performance of a public official function or activity.</p> <p>d. In addition to other rights or remedies under this Agreement or at law, SPONSOR may terminate this Agreement if Institution breaches any of the representations or warranties contained in this Section or if SPONSOR learns that improper payments are being or have been made to Public Officials or any other third party by Institution or any individual or entity acting or its behalf.</p> <p>e. For the purposes of this Agreement, "Public Official" means any officer or employee of a government, a public international organization or any department or agency thereof, or any person acting in an official capacity, including, for a public agency or enterprise; and any political party or party official, or any candidate for public office.</p>	<p>1. This Agreement shall be interpreted and governed by the laws of Taiwan, without regard to conflict</p>
22	<p>22. APPLICABLE LAW AND JURISDICTION/ARBITRATION</p> <p>This Agreement, and all disputes and/or claims arising under this Agreement, shall be interpreted</p>	



	<p>and governed by the laws of Taiwan, without regard to conflict of laws principles.</p> <p>The parties will endeavour to settle amicably any dispute having its origin in this Agreement. In case a dispute is brought before a court of law, the courts of Taiwan will have sole jurisdiction over the litigation, and XXX District Court shall be the court of first instance.</p> <p>OR</p> <p>Any dispute, controversy or claim arising out of or relating to this Agreement which cannot be resolved within thirty (30) days by mutual consent of the parties, shall be referred to arbitration before the Arbitration Association of the Republic of China ("ROC") and shall be settled under the administration of the Arbitration Association of the ROC in accordance with the procedures of the ROC Arbitration Law, Arbitration Rules of the Arbitration Association of the ROC and related enforcement rules in force. The arbitration shall take place in Taiwan and shall be conducted in the language of Mandarin Chinese.</p>	<p>of laws principles.</p> <p>2. Dispute could be solved either by court process or by arbitration.</p>
23	<p>23. MISCELLANEOUS</p> <p>23.1 Entire Agreement This Agreement, including all exhibits hereto, contains the entire understanding of the parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. In the event of a conflict between provisions of the Protocol and this Agreement or any exhibits hereto, the Protocol shall control with respect to matters of science, medical practice, and Study subject safety. In all other matters, the provisions of this Agreement shall control. None of this Agreement or any of its terms, including any attachment or exhibit hereto, may be amended, restated or otherwise altered except by written agreement signed by the parties.</p>	

23.2 Severability If any provision, right or remedy provided for herein is held to be unenforceable or inoperative by a court of competent jurisdiction, the validity and enforceability of the remaining provisions will not be affected thereby.

23.3 Waiver Waiver or forbearance by either party with respect to a breach of any provision of this Agreement or any applicable law shall not be deemed to constitute a waiver with respect to any subsequent breach of any provision hereof.

23.4 Notice Any notice required or permitted to be given hereunder by either party hereto shall be in writing and shall be deemed given on the date received if delivered personally, by recognized overnight courier, or by facsimile, or five (5) days after the date postmarked if sent by registered or certified mail, return receipt requested postage prepaid, to the following address:

If to Institution: [Insert Institution's Name]

[Insert Institution's Address]

Telephone: [Insert Institution's Phone Number]

Facsimile: [Insert Institution's Facsimile Number]

Attn: ..


If to Investigator: [Insert Investigator's Name]

[Insert Investigator's Address]

Telephone: [Insert Investigator's Phone Number]

Facsimile: [Insert Investigator's Facsimile Number]

Attn: ..

	<p>If to Sponsor: [Insert Sponsor's Name] [Insert Sponsor's Address] Telephone: [Insert Sponsor's Phone Number] Facsimile: [Insert Sponsor's Facsimile Number] Attn:</p> <p>Any party may change its notice address and contact person by giving notice of same in the manner herein provided.</p>	
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