**Clinical Study Agreement**

Institution:
Institution Contract Representative: Taipei Medical University
Principal Investigator:
SPONSOR:
Protocol No.:

**Clinical Study Agreement**

Parties to the Agreement:

Taipei Medical University Hospital

Taipei Municipal Wanfang Hospital

Taipei Medical University-Shuang Ho Hospital, Ministry of Health and Welfare (the “Party A”)

(the “Party B”)

Whereas, Party B authorizes Party A for the conduct of a clinical study entitled “  ” (the “Study”). The details of the Study are as shown in the Appendix 1 (the “Protocol”). Party A and Party B have entered into this Clinical Study Agreement (the “Agreement”) in good faith, and hereby agree as follows:

**Article 1: Approval of Ethics Committee**

* 1. Party B shall obtain the approval of Taipei Medical University - Joint Institutional Review Board (the “Ethics Committee”) before the initiation of the Study. Cases which are controlled by the Ministry of Health and Welfare shall require the approval of the central competent health authority.
	2. In no event may Principal Investigator conduct the Study on anyone before obtaining the aforesaid approval.
	3. Principal Investigator shall conduct the Study as set out in the Protocol that has been approved by the Ethics Committee. Any amendment to the Study or its schedule shall require consents from both Party A and Party B, as well as the approval of the Ethics Committee. Cases which are controlled by the Ministry of Health and Welfare shall require the approval of the central competent health authority.
	4. Principal Investigator shall perform the Study in compliance with applicable laws and regulations and guidelines.

**Article 2: Institution and Principal Investigator**

* 1. The Institution of this Study is:

Taipei Medical University Hospital

Taipei Municipal Wanfang Hospital

Taipei Medical University-Shuang Ho Hospital, Ministry of Health and Welfare

* 1. The Principal Investigator of the Study is: Dr. J. Timothy Qiu of Taipei Medical University Hospital.
	2. Party A and its personnel associated with the conduct of the Study shall fully comply with the terms of this Agreement, and shall be responsible and liable for any breach or damage incurred therefrom.

 **Article 3: Study Duration**

* 1. The Study is expected to be initiated from to .
	2. Any need for an extension or change of the Study duration shall require written consents from both Party A and Party B.

 **Article 4: Study Budget**

* 1. Party B shall pay an amount of NTD       (exclusive of VAT; and the same shall apply below) as the study budget required for the Study. Party B shall also make payments for any “Other Study-related Fees (Per Occurrence)” incurred during the conduct of the Study. The aforesaid study budget as required for the Study and “Other Study-related Fees (Per Occurrence)” shall collectively be referred to as “Study Budget”, their details and contents are as shown in the Appendix 2 (the “Budget Table”).
	2. Any taxes or transaction fees arising out of the Agreement shall be borne by Party B.
	3. The Study Budget shall be planned and utilized by Party A. After the commencement of the Study, Party B may no longer request for return of any non-refundable fees listed in the Budget Table.
	4. If Party A or Party B, due to any actual circumstance, believes the Study Budget requires further adjustments, it shall provide relevant information to the other Party during the Study, and adjust the Study Budget after obtaining the other Party’s written consent.

 **Article 5: Payment Method**

* 1. Party B shall pay the Study Budget to Taipei Medical University in installments according to the requirements stated in the Budget Table and this Article. If Party B fails to perform its payment obligation under the Agreement, Party A may impose a delay punitive damage at the rate of 1% of the total Study Budget for each day of delay, with a maximum delay punitive damage of 20% of the total Study Budget, however.
		1. The 1st Installment Payment: NTD      . Party B shall make a single payment to Taipei Medical University by the immediate cheque or wire transfer within thirty (30) days upon the execution of the Agreement.
		2. The 2nd Installment and Subsequent Installment Payments: Party B shall make a single payment of the respective installment in accordance with the payment deadline, amount payable and payment methods as specified in the payment notice issued by Taipei Medical University.
	2. At the end of the Study, Taipei Medical University will perform the reconciliation of Study Budget in accordance with the requirements of the Budget Table against with the actual conduct of the Study. Upon the reconciliation, if the Study Budget is remaining, it will be returned by Taipei Medical University. Any deficiency upon the reconciliation shall by supplemented by Party B.

 **Article 6: Provision of Study Materials and Information**

* 1. Party B shall provide Party A with sufficient amounts of study products, equipment, devices and information as stipulated in the Protocol for the conduct of the Study. Except as otherwise stated herein, the ownership of such materials and information will be owned by Party B.
	2. The materials and information obtained under the preceding paragraph by Party A and its personnel associated with the conduct of the Study shall not be used for any purposes other than for this Study.

 **Article 7: Understanding and Assistance during the conduct of the Agreement**

* 1. If Party B needs to know the implementation status during the course of the Study, it shall inform Party A fifteen (15) days in advance of its intent. Party A shall do its best effort to provide assistance, give detailed explanation and provide the relevant data.
	2. If, during the conduct of the Study, Party A needs Party B to provide personnel, study materials and information, as well as assistance in other relevant matters, as necessary for the Study, Party B shall do its best effort to cooperate with Party A.
	3. Party B shall cooperate with Party A in any audit of clinical trials.
	4. The Agreement shall not be construed as limitation of freedom to Party A and its personnel associated with the conduct of the Study (whether such personnel is under payroll or not) of participating in similar cases other than those of the Agreement or Party B.

 **Article 8: Confidentiality Obligation**

* 1. Both Party A and Party B agree that they will, with the due care of a good administrator, maintain and securely protect any and all confidential information and other relevant data (including this Agreement) that they know or possess as a result of the Study. They will not disclose or provide such information to any third party without the other Party’s written consent.
	2. Both Party A and Party B agree and undertake that all confidential information that they know or possess through the Study shall be used only for the legitimate purposes as contemplated in this Agreement, and only the individuals who are directly responsible for the performance of the Agreement have the right to access such confidential information. In the meantime, such individuals shall also be requested to maintain the same degree of confidentiality obligation hereunder.
	3. Both Party A and Party B agree and undertake that, during the term of this Agreement and after its expiration, termination or cancellation, they shall not neither disclose or provide any confidential information nor disclose all study subjects’ names or medical record numbers which may link to their identities or health conditions to any third party, except that such information is required by laws or regulatory authorities.

 **Article 9: Ownership and Interest of Study Results**

* 1. Study data and documentation obtained by the Principal Investigator from the conduct of the Study shall be jointly owned by Party A and Party B. Subject’s medical records, however, are owned by Party A. Upon the termination of the Study, the Principal Investigator shall retain and handle the source data of such study data and documentation in accordance with applicable laws and regulations.
	2. The intellectual property right of any technology or its derivatives used in the conduct of the Study by Party A, and any rights derived therefrom shall be owned by Party A. For the ownership of any study results generated by the Study and the intellectual property rights thereof (hereinafter collectively as the “Study Results”), it is agreed as follows:

 The Study Results shall be owned by Party B.

1. The Study Results shall be jointly owned by Party A and Party B, with a distribution ratio in relation to interest derived therefrom,      % for Party A and      % for Party B (the “IP Ownership Ratio”).

2. Once the other Party’s written consent is obtained, Party A or Party B may submit applications to the competent authorities for intellectual property rights, such as patent and circuit layout rights with respect to the Study Results (the “Intellectual Property Rights”). The Parties shall share the payments for the application fees and maintenance expenses arising from such Intellectual Property Rights in accordance with the IP Ownership Ratio stated above or a ratio otherwise agreed upon.

3. Neither Party may authorize or assign any of the Intellectual Property Rights resulting from the Study Results to any third party without the other Party’s written consent; and without Party A’s written consent, Party B may not implement any of the Intellectual Property Rights resulting from the Study Results on its own, except for its internal use.

4. All substantive and procedural matters relating to the management, application and distribution of interest of Study Results shall be stipulated in a separate agreement.

 **Article 10: Publication or release of Study Results**

* 1. Party A and the Principal Investigator are entitled to publish the Study Results; the copyright of such publication shall be owned by the presenter. The presenter, in its own discretion, may decide the content of its publication and the order of authorship, but clear acknowledgement of items provided and supported by Party B shall be specified. Such publication shall be notified to Party B fifteen (15) days prior to its publication, and will only be commenced upon Party B’s consent. If such publication is in the area of academic publication, Party B may not refuse the publication except for the content thereof involving any business secrets of Party B.
	2. Party A and the Principal Investigator may use the study data, documentation and Study Results obtained from the conduct of the Study in compliance with their statutory obligations, or for the purpose of academic research or providing the subjects with treatment care.
	3. To the extent of the Study and its Study Results, except upon Party A’s prior written consent, Party B shall neither make any third party aware of any connection between Party A and Party B in any way (including but not limited to commercial promotion, e.g. public marketing, promotion or advertising materials, inner/outer packaging or web pages of products or services), nor use Party A’s faculty, staff, or their affiliations’ names, faculty logos, trademarks or other identifications publicly. However, such limitation shall not apply to the registration of the Study on the website as required by law, or on other websites requested by the guidelines of the International Committee of Medical Journal Editors (ICMJE), or the use thereof as required by any government authority.
	4. Any breach of the preceding requirements by Party B shall be penalized with a punitive damage in the amount of 1.5 times the total Study Budget. For a punitive damage that is less than NTD 1,000,000 under the above calculation, it shall be imposed as NTD 1,000,000.

 **Article 11: Specimens and Samples Collected in the Study**

Except otherwise permitted to be retained or reused by law, or upon the study subject’s consent, any biological specimens, personal data or its derivatives of study subjects shall be destroyed immediately at the end of the Study.

 **Article 12: Reporting Obligation**

* 1. The Principal Investigator shall notify and make Party B aware within 24 hours of any serious adverse event such as death or life-threatening event of the subject occurring in the course of the Study, and shall provide assistance in the report to the competent authority. The Principal Investigator shall report to the Ethics Committee within seven (7) days of becoming aware of such event, and provide a written report within fifteen (15) days.
	2. Any scheduled Data and Safety Monitoring Plan/Board (DSMP, DSMB/DMC or other similar boards) of Party B, if any, shall require to be reviewed and approved by the Ethics Committee. A routine monitoring report shall be provided to Party A within thirty (30) days after conduct of the monitoring for the Principal Investigator to send them along with the interim report to the Ethics Committee.
	3. In the event of Party B’s monitoring activity becoming aware of any serious adverse reaction of the subject or any new finding that may harm the safety of the subject, or affect the conduct of the Study or the approval of the Ethics Committee to continue with the Study, Party B shall notify the Principal Investigator, Party A and the competent authority within seven (7) days of becoming aware thereof, and shall provide relevant written data within fifteen (15) days to Party A for its report to the Ethics Committee; Party B shall also report to the central competent health authority and the Ethics Committee in accordance with the prescribed scope and deadline of applicable laws and regulations of the Republic of China.
	4. If Party B, within two (2) years after the end of the Study, becomes aware from the Study Results of any information that has direct impact on the subject safety, Party B shall report such finding to Party A within fifteen (15) days and provide subsequent handling measures.
	5. Party B shall submit relevant reports of the Study in accordance with the requirements of the Ethics Committee.

 **Article 13: Termination of this Agreement**

* 1. If it is not able to continue the conduct of this Agreement due to any reason from either party, this Agreement may be terminated by a thirty (30) - day prior written notice given by such party and after receiving the other party’s consent. However, if it is likely to endanger the subject’s safety, this Agreement shall be terminated forthwith after a notice is delivered to the other party. The same shall apply to the amendment.
	2. Upon the termination of the Agreement as described above, Party B may not request for return of any non-refundable fees listed in the Budget Table or fees for items that are already performed. Both Party A and Party B agree to perform reconciliation of actual Study Budget spent in accordance with the standard of the subject enrollment as listed in the Budget Table against with the actual number of enrollment. Any overpayment will be refunded and a supplemental payment will be made for any deficiency.
	3. In the event of default or violation by either Party, unless otherwise provided herein, if the defaulting party cannot cure such default or violation within a reasonable period of time given by the other Party, the other Party may terminate the Agreement; and the defaulting party shall be liable for the damage and compensation resulting from such default or violation.
	4. The subsequent ownership of the Study Results after the Agreement is terminated shall be executed in accordance with the provisions under Article 9 hereof.

 **Article 14: Indemnification**

* 1. Party B shall indemnify against any damages suffered by the subject as a result of participating in the Study, provided that Party A and its personnel associated with the conduct of the Study have properly followed the steps outlined in the Protocol when conducting the Study; Party B shall be liable for the compensation. The fee spent by Party B for treatment of the subject shall also be borne by Party B. Party B shall indemnify Party A and its personnel associated with the conduct of the Study against any and all losses incurred from such event (including costs of settlement with the claimant, compensation ruled by a court of law, expenses arising from suits, attorney fees or other relevant fees).
	2. For any damages suffered by the subject during the participation in the Study as a result of the willful misconduct or negligence, or non-compliance of the Protocol by the Principal Investigator or Party A’s personnel associated with the conduct of the Study, Party A shall be responsible for the subsequent handling of the event and indemnify against such damages.
	3. Except for the indemnities stated above, in no event shall Party A be responsible to Party B for any of its damages or losses, or losses of interest or profits.

 **Article 15: Insurance Obligation**

* 1. Party B shall subscribe commercial general liability insurance, self-insurance or clinical trial insurance for the Study, and provide written evidence of such insurance to Party A before the Study is started. Such insurance shall provide coverage sufficient for the indemnification responsibility of Party B hereunder.
	2. In the event of cancellation, non-renewal or change of such insurance, Party B is required to notify Party A at least fifteen (15) days prior to the occurrence of such event. Party A shall have the right to terminate the Agreement if an equivalent alternative insurance is not found by Party B within such period of fifteen (15) days.

 **Article 16: Transfer of Interest**

Any transfer of Party A or Party B’s rights and obligations hereunder shall be notified to the other Party thirty (30) days prior to the event with documents relevant to such transfer executed.

 **Article 17: Severability**

In the event that any provision contained in this Agreement is deemed invalid by applicable laws and regulations, the remaining provisions shall still remain in full force and effect.

 **Article 18: Representation and Warranty**

* 1. Party A represents and warrants that all of its personnel associated with the conduct of the Study have any and all qualification, approvals, permits, licenses and other requirements under the applicable laws and regulations of the Republic of China throughout the conduct of the Study.
	2. Party B warrants that all the drugs provided in the Study are in full compliance with the Medical Care Act, Good Manufacturing Practice and other applicable requirements. No matter whether the drugs are manufactured or imported by Party B, Party B agrees to assume the responsibilities of a manufacturer and an importer towards the subjects under the Consumer Protection Act. The subject may also exercise his/her rights directly towards Party B under such Act.
	3. Party B shall provide the “Investigator’s Brochure” that details the physical and chemical properties of the investigational drug, its pharmaceutical profile, toxicology and safety information when used in animals and humans, pharmacokinetics and pharmacodynamics data, and information from the pre-clinical study, and shall provide the standard operation procedure which conform to the relevant requirements of the Good Clinical Practice, Medical Care Act and Pharmaceutical Affairs Act.
	4. During the Study, if any relevant information (including the safety information and new therapies) becomes available, Party B shall notify Party A in writing immediately.
	5. Party B warrants that the study materials and data are true and do not infringe upon the patent, trademark, copyright, or trade secret claimed by a third party.

 **Article 19: Force Majeure**

For the inability to fulfill the Agreement caused by floods, fires, storms, earthquakes, or others that cannot be attributed to any party, s not obligated for reimbursement or liable for delay.

 **Article 20: Compliance with Applicable Laws**

Both Party A and Party B shall comply with ethical principles relating to clinical trials and other applicable laws and regulations during the conduct of the Study.

 **Article 21: Effect of Appendices and Entire Agreement**

* 1. The appendices shall be deemed as a part of this Agreement.
	2. If there is change to the appendices, the most updated version approved by the Ethics Committee thereof shall prevail. However, cases which are controlled by Ministry of Health and Welfare are subject to the most updated version of the appendices approved by the central competent health authority.
	3. This Agreement, together with the appendices hereto, constitutes the entire agreement between the Parties with respect to the Study. Any items agreed upon by the Parties prior to the execution of this Agreement but not specified herein or in the appendices attached thereto shall not be binding on the Parties hereto.

 **Article 22: Agreement Interpretation and Dispute Resolution**

* 1. This Agreement shall be construed in accordance with and be governed by the laws of the Republic of China. Both Party A and Party B agree to resolve any questions or disputes under or in connection with this Agreement in good faith.
	2. In the event of any litigation arising out of or in connection with this Agreement, Party A and Party B agree that Taiwan Taipei District Court shall be the court of first instance.

 **Article 23: Contact Management**

* 1. Any notice or request under this Agreement shall be delivered in writing to the following respective place and personnel (the “Contact Person”), and shall be deemed as delivered once such notice or request are delivered to the Contact Person:

**Party A**

Unit: Joint Clinical Research Center
Contact person:
Tel: 02-6638-2736 Ext.
Address: 17F., No. 172-1, Sec. 2, Keelung Rd., Daan Dist., Taipei City

Email：

 **Principal Investigator**
Contact person:
Tel: ext.
Address:

Email：

**Party B**
Unit:
Contact person:
Tel:
Address:

Email：

* 1. Either Party shall notify the other Party’s Contact Person in writing of the updated information if there is any change to its Contact Person or contact information.

 **Article 24: Duplicates**

This Agreement shall be executed in four (4) duplicate originals, with Taipei Medical University, Party A, Party A’s Principal Investigator and Party B each holding one original.

 **Article 25: Miscellaneous**

Any matters not provided herein shall be resolved according to applicable laws and regulations or be added upon mutual consents of both Parties.

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Signature page to follow

**Signature Page**

 **Parties to this Agreement**

**Party A**  **Hospital** (Contract Representative: Taipei Medical University Representative: President Chien-Huang Lin)

Tax ID No.:

Address:

Principal Investigator: J. Timothy Qiu

**Party B:**

Representative:

Address:

MM/DD/YYYY

**Appendix 1: Protocol**

**Appendix 2: Budget Table**