CLINICAL RESEARCHAGREEMENT

(Signed by three parties – for Database analysis related human research cases)

This agreement is signed by the following parties:

Party A: CHANG GUNG MEDICAL FOUNDATION (TAIPEI, LINKOU, KAOHSIUNG, CHIAYI, YUNLIN, KEELUNG, TAOYUAN) CHANG GUNG MEMORIAL HOSPITAL**(OR)** New Taipei Municipal TuCheng Hospital (Built and Operated by Chang Gung Medical Foundation) **(OR)** Kaohsiung Municipal Ta-Tung Hospital 【Please fill in according to the signatory hospital area】

Party B:

Party C: Doctor (Principal Investigator)

In order to jointly research and develop [the name of the protocol] related to this research (hereinafter referred to as "the research and development"), the three parties have entered into this agreement for compliance, the terms and conditions are hereby as follows:

**Article 1 Content of research**

Party A and Party C agree to carry out this research and development in accordance with the protocol([name of the protocol]; protocolas attachment 1), and no additional research is allowed. Any amendments must be implemented after the approval of the Institutional Review Board committee. If there are any additions, deletions and modifications to the protocol, Party A and Party C shall notify Party B in advance in writing.

This agreement IRB Original Case Number:

Parties’ employees promise that they never have and will not get any unfair benefits, obtain or reserve any obligations, commercial benefits, public and official functions or activities or take other improper actions in relation to this experiment.

**Article 2 Research and development period**

This clinical research agreement ("this agreement") will take effect when it is fully signed ("Effective Date").

**Article 3 Cooperation**

1. Party A shall be responsible for providing .

2. Party B shall be responsible for providing .

3. The relevant expenses shall be borne by the party , totaling NT dollars. (Or) The research cooperation model is implemented in the form of combined review relative to their respective subsidies. Party A’s expenditure plan totals NT$ , Party A’s expenditures on site and equipment, etc. are worth NT$ ; Party B’s expenditure plan totals NT$ , Party B’s expenditures on venues, equipment and instruments, etc., are valued in NT$ .

4. If there is a need to add, delete or modify the cooperation method, it should be agreed in writing by parties.

5. Party B guarantees that the software and hardware, systems, platforms, equipment, products and any other materials, resources or information (hereinafter referred to as Party B’s materials) provided by Party B do not infringe the intellectual property rights, trade secrets or other rights of others, and if there are any If a third party claims to infringe its rights, Party B shall be responsible for excluding and ensuring that Party A is not harmed.

6. Party B guarantees that neither itself nor any third party will obtain any information from Party A due to Party A’s use of Party B’s materials and "this result" (as defined later)(Including but not limited to operation records, history, test images, text, test results, etc.). (Applicable when the materials provided by the manufacturer or "this result" need to be connected or installed in the system or equipment of the hospital)

7. Party B guarantees that the materials of Party B meet the safety requirements of applicable laws and regulations.

8. Party B guarantees that the installation, testing and use of Party B's materials and "this result" will not affect the normal operation of Party A's existing system, nor will it damage its existing programs and data. Party B shall first check and ensure that Party B’s materials do not contain any malicious programs (including but not limited to viruses, worms, Trojan horses, spyware, etc.) and/or covert channels. (Applicable when the materials provided by the manufacturer or "this result" need to be connected or installed in the system or equipment of the hospital)

9. The ownership of the equipment purchased for this research and development project belongs to one of the investors. (Applicable when there are instruments and equipment)

If the sponsoring funding of Party B is paid in New Taiwan Dollar, please remit the sum to Hua Nan Commercial Bank Minsheng Branch according to the remittance account and method announced on the website of this HOSPITAL; if it is not paid in New Taiwan Dollar, Institution only takes US Dollar as the collection currency, collection information are as follows:【Please adjust the receiving information according to the actual sending bank】

Beneficiary bank: Yuan Ta Bank LTD

Branch: International Business Dept.

Account name: CHANG GUNG MEDICAL FOUNDATION LINKOU CHANG GUNG MEMORIAL HOSPITAL

Bank account: 0200102121815

**Article 4 Intellectual property**

Any research and development results resulting from the implementation of this research and development, including but not limited to technical data, patent application rights, patent rights, copyrights, trade secrets and other intellectual property rights, various forms of related products (referred to as "this result"), etc., All belong to the ＿＿ party. (Or) According to the contribution ratio of both parties to "this research and development", the attribution of "this result" is based on the principles of Party A % and Party B %; the application for intellectual property rights also requires both parties A and B to be the applicants, and the proportion of cost sharing is based on the intellectual property rights The attribution ratio is the principle. The term “fee” includes application fee, supplementary correction or reply fee, certificate fee, first (three-year) annual fee, office handling fee and other related fees that should be paid according to laws and regulations.

"This result" and those born from using the funds or resources invested by Party A, all institutions in Party A's system (including the institution under management and "cooperation alliance institutions") and Party B can use it internally for free (including but not limited to: Use "this result" to provide related medical services, etc.), and Party B shall provide maintenance services free of charge. If Party B subsequently develops any updated version by itself, Party B shall also provide it free of charge and assist Party A in upgrading and maintenance (or Party B shall use the market’s best The preferential terms provide Party A's upgrade and maintenance services). In addition, if Party A transfers its rights to Party B or waives the patent rights of a specific region or country, it still enjoys this right. However, if any party intends to use the "This Result" for other commercial or profit-making purposes, it shall be handled in accordance with Article 6.

After the signing of this agreement, if any party agrees to invest additional funds (the funds invested without the other party’s consent or beyond the agreed scope shall not be included in the calculation or used as the basis for adjusting the proportion of intellectual property rights), Party A and Party B agree to the following contribution The principle of proportional distribution redistributes the intellectual property rights in this case, and re-signs the agreement based on the adjusted proportion of the ownership of the intellectual property rights (if either party refuses to re-sign the cooperation contract, the proportion of intellectual property rights should still be adjusted according to the following principles):

1.60% of the intellectual property rights shall be allocated according to the proportion of the capital contribution of Party A and B in the total funds of the cooperative R&D project (for example, if one party’s capital contribution accounts for 30% of the total funds, 18% of the intellectual property rights shall be obtained).

2. The remaining 40% of the intellectual property rights will be distributed according to the originally negotiated proportion and will not be adjusted.

**Article 5 Academic publication (AAHRPP 1.8 D)**

Party A has the right to publish the results of research and development, continuous academic research, and use the data and results obtained from research and development for the purpose of providing treatment and care for the human subjects of the research and development. The ranking and content (including scientific conclusions and professional judgments) of the authors proposed by Party A for academic publication shall be determined by it, but the items and content of assistance provided by Party B shall be stated. If Party A and Party C (including co-hosts) intend to publish clinical trial results or data resulting from the implementation of this research in academic journals, seminars, press conferences and other public occasions, they should be published the day before the academic journals and seminars The day before the meeting or press conference, the content to be published shall be provided to Party B for review. Party B has the right to provide opinions and request Party A and Party C (including co-investigators) to amend it in the following circumstances.

1. To ensure the correctness of the content of academic journals, seminars, and press conferences;

2. To ensure that Party B's confidential information is not improperly disclosed;

3. To protect Party B's intellectual property rights;

4. In order to put other relevant supplementary information together.

[The following description can be modified or deleted depending on the actual situation of the case]

If Party B believes that the results of the research and development may have the "this result" stipulated in Article 4 and obtain individual rights, it can request Party A and Party C (including co-investigator) in writing when Party B receives the content to be published or The patent application documents related to this research and development shall not be disclosed within days from the time when the patent application documents related to this research and development are complete. In order to facilitate the protection of the patent right , Party A and Party C (including co-investigators) shall not refuse without justified reasons.

For papers related to this research and development published in academic journals, the copyright of the paper should belong to Party A and Party C

**Article 6 Profit distribution**

【Either party shall obtain the consent of the other party before using the "this result" as the use of income for profit or other purposes, but Party A may use the "this result" to provide related medical services in accordance with Article 4, and the income obtained , No need to be allocated to Party B. 】 Or【Either party’s use of "this result" (such as authorizing a third party to develop and use or Party B's commercialization of "this result " for external sales for profit, etc.) shall be distributed according to the following proportions (except for Party A in accordance with Article 4 The agreed use of "this result" to provide related medical services income does not need to be distributed to Party B in accordance with this article):

(1) Party A: %.

(2) Party B: %.

After the income in the preceding paragraph is distributed to Party A and Party B, both parties may handle it in accordance with their respective regulations and distribute it to creators, inventors or designers.】

**Article 7 Logo and use**

Before obtaining the written consent of the other party, one party shall not quote the name, name, Court emblem or other means of characterization; nor shall it indicate any connection between the two parties in any way. If one party violates the provisions of this article, it shall pay punitive damages to the other party.

**Article 8 Confidential information**

In order to implement the protocol, one of the parties to this agreement shall disclose to the other party all relevant information, including but not limited to investigators’ information, protocol, data, images, reports, messages, graphics, prescriptions and manufacturing processes, etc. (below (Referred to as confidential information), all such confidential information should still belong to the property of the disclosing party.

The “confidential information” mentioned in the preceding paragraph does not include (1) the information that either party can prove in writing before signing this agreementor before it is disclosed (2) the information obtained by either party’s independent research and development (3) either party can be justified Information obtained by the channel from a third party with legal rights, or knowledge or information that has been disclosed in the public domain at the time of disclosure.

**Article 9 Confidential Clause**

Party A, Party B, and Party C agree to use the duty of care of a reasonably prudent person to strive to maintain and properly keep all confidential information and other related materials (including this agreement) that they know or hold due to this research and development. It shall not be disclosed or delivered to any third party without the written consent of the disclosing party.

Parties agree and promise that all confidential information known or held as a result of this research and development should only be used for the legal purposes specified in this agreement, and such confidential information should only be disclosed to persons who need to know for the purpose of conducting clinical trials ( Including co-investigators), and at the same time, they should be required to comply with the confidentiality obligations stipulated in this article.

Parties agree and promise that, during the term of this contract and after the expiration, termination or cancellation of this agreement, unless this agreement provides otherwise for the performance of this agreement, they shall not disclose or deliver confidential information obtained as a result of this partnership to a third party, but If the disclosure or delivery is in accordance with the law, this is not the case.

Parties promise that during the term of this contract and after the expiration, termination or cancellation of this agreement, except in accordance with the law or the requirements of the competent authority, they will never disclose the names and medical records of all patients included in this development and research , as well as the true identity and identity of the patients. Information related to the condition.

Parties promise to destroy or return the confidential information of other parties during the term of this agreement and after the expiration, termination or cancellation of this agreement.

Either party may require the other party to issue a written declaration and guarantee that the confidential information held by the other party has been destroyed.

**Article 10 Indemnification**

In the event of related damages caused by this research and development, each party shall be liable for related damages to other parties based on their own attributable reasons.

Party B can only use the biological specimen in the manner permitted by the obtained human subject’s consent document, and shall not use it for other purposes. If Party B violates the agreement, it shall immediately terminate the violation of the use of the biological specimen, and shall compensate the site All damages and processing (whether successful or not) all legal proceedings (including any reasonable legal, expert fees and expenses) costs.

**Article 11 Termination**

Either party can unilaterally terminate this agreement, but the other party must be notified in writing 90 days in advance.

**Article 12 Dispute handling**

Any disputes arising from the research and development should be jointly raised with the host of this research and development. Both parties should follow the principle of good faith and seek a feasible solution through negotiation to resolve the dispute in good faith. If the dispute cannot be resolved through negotiation, it can be resolved through judicial.

**Article 13 Responsibility**

1. Party A and Party B do not make any express or implied guarantees regarding the commercial capabilities of the "This Result" and derivative products or their use.

2. Neither party is responsible for losses that are not attributable to itself. When an event of force majeure occurs, the other party should be notified as soon as possible to conspire in the best interests of both parties. Parties can negotiate together to delay the progress of their research and development according to their actual needs.

**Article 14**  **Miscellaneous Clause**

1. Parties hereto may revise or supplement through negotiation matters not mentioned herein according to laws, practices and the principle of good faith.

2. All disputes arising from the performance of this agreement should be settled through friendly negotiation, and if there is no agreement upon the negotiation or any party refuses to coordinate, the dispute shall then be submitted to the Part A’s local courts as the court of first instance where the agreement is reached for settlement, during which ROC laws shall govern.

3. The Attachment and Protocol shall be parts of the agreement and invalid in the case of any discrepancy with the Agreement.

4. The agreement is made in triplicate, each of which shall be deemed equally authentic, and each party shall hold one copy.

Party A: CHANG GUNG MEDICAL FOUNDATION (TAIPEI, LINKOU, KAOHSIUNG, CHIAYI, YUNLIN, KEELUNG, TAOYUAN, TUCHENG) CHANG GUNG MEMORIAL HOSPITAL**(OR)** New Taipei Municipal TuCheng Hospital (Built and Operated by Chang Gung Medical Foundation) **(OR)** Kaohsiung Municipal Ta-Tung Hospital 【Please fill in according to the contracted district】

Director:

Address: Tel:

Party B:

Address: Tel:

Party C: Clinical Experiment Principal Investigator Legal Representative:

Address: Tel:

**Date: (the Republic of China calendar)**

Appendix 2 – Budget

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| --- | --- | --- |
| In the \_\_\_\_\_\_ Year  (List of sponsored items and amount, please compile funding of each year) | | |
| Item | Funding Budget | Explanation  (The following are common sponsored funding items. Please amend according to the actual sponsored items) |
| Staff Fee (A) |  | (1)X(S)**M**RP research：Limited to compilation of the fee of the Principal Investigator, if no fee of the Principal Investigator is compiled, “Statement that no fee of the Principal Investigator is charged” should be attached.  (2)X(S)**P**RP research：Principal Investigator initiated (included partial sponsorship from sponsors) research shall not be allocated the fee of the Principal Investigator, and “Statement that no fee of the Principal Investigator is charged” should be attached. If the research nurse or research assistant personnel expenses are sponsored by a sponsor and appointed by the PI, they may be allocated here and paid. |
| Fee of consumable materials and medicines (E) |  | Taking Human Subject-related expenses as the principle, such as registration fees of subjects, expenses related to outpatient service, test/examination fees, treatment fees, related consumables for treatment (e.g. dressing), hospitalization expenses, nutrition fees, traffic/accommodation allowance of subjects and caregivers, medical service fees (e.g. image interpretation/analysis fee, technical service fee, etc. to be compiled according to charging standards formulated by various departments of this Hospital and incorporated into incomes of this Hospital and then allocated to individuals according to their performance in each department), health education fee, charges for diagnosis and treatment by doctors, and handling and storage costs of human subjects’ samples (funding of which is to be compiled according to charging standards of this Hospital), etc.The standard of various clinical trial test/examination fees: health insurance payment items are priced at 1.5 times the premium, and health insurance non-payment items are priced at the hospital's own expense price plus 1.5 times. |
| Instrument and equipment fee (F) |  | Procurement of clinical trial supplies, equipment, instruments and maintenance fees. |
| Other fee of Study (Z) |  | (1)Compilation according to charging standards of this Hospital: Expenses of information system support, biostatistics support, etc.; if an application needs to be submitted to the tissue bank for samples in the research, sample application review fee (NT$ 2,000) per application per case needs to be compiled.  (2)Actual payment according to the amount of expenses:  A.Study related office consumables: Seal engraving fee, stationery fee, photocopying fee, photocopying paper, postal and telecommunications fee, related consumables of MFP/fax machine, storage cabinet of documents related to the research, etc.  B.Study related equipment or consumables: Experimental consumables or reagents, blood drawing peripheral consumables (e.g. sterile cotton ball, gauze, cotton swab, injection syringe, blood sampling scalp needle, medical tape, etc.), study instrument calibration fee, glucose meter/blood pressure meter/oximeter/ear thermometer/thermometer/centrifuge and related consumables, refrigerator, cooler bag, light-avoiding medicine box, goggles, alcohol pad, gloves, research locker, zipper bag, etc.  C.Computer peripheral consumables and maintenance: Tablet computer, computer and computer peripheral equipment fees, scanner, DVD/CD-RW, information software, USB, battery, CD, etc.  D.Study related training: Clinical trial related training and certification examination registration fees, such as BLS course, GCP course, etc.  E.Study-related travel expenses: Sponsoring targets shall be limited to be Principal Investigator and experiment team members, and the contract shall specify the sponsored items (such as travelling expense, accommodation expense, meal charge, etc.) and sponsorship amount. If not specified, “Management Measures on Business Trips” of this Hospital shall be followed.  F.Others: Clinical trial liability insurance premium, document storage fee, internet access fee, remittance charge, IRB review fees for XPRP researches, etc. |
| Management fee(K) |  | For total funding less than NT$ 1 million, 15% of the total paid-in sum is allocated according to the account in the current year [management fee = total funding ÷0.85×0.15]; for total funding more than NT$ 1 million, 5% is allocated as management fee [management fee for the part in excess of NT$ 1 million = (total funding-1 million) ÷0.95×0.05]; the allocation of NT$ 10,000 from the annual planned management fee shall be the lower limit (including without the aforementioned sponsoring funding compiled (Items A, E, F, Z)) in the current year . |
| Fee of researchers employed by this Hospital (Q) |  | They refer to the personnel costs of the research assistant and research nurse appointed by the Clinical Trial Center under the entrustment of the Sponsor. After the Sponsor compiles the funding budget of these costs, the reasonableness of which shall be reviewed by the Clinical Trial Center. If there is no need to appoint a research assistant and research nurse to assist in the implementation of the scheme, the Principal Investigator’s statement on having not appointed a research assistant / research nurse shall be attached. |
| Total  in \_\_year |  |  |