Please declare yourself within the Contractual Provision Items:

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| --- | --- | --- | --- | --- | --- | --- | --- |
| Contractual Provisions | Deliverer | | | Examined by the Clinical Trail Center | | | |
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| 1.This is a change of the Contract. It is not necessary to be filled out. |  |  |  |  |  |  |  |
| 2. Specify the name of the experiment plan, which should be the same as that in the IRB Approval Letter. |  |  |  |  |  |  |  |
| 3. Specify the name of the investigator, which should be the same as that in the IRB Approval Letter. |  |  |  |  |  |  |  |
| 4. Nurse practitioner or assistants have been provided by the Hospital’s Clinical Trial Service Center. |  |  |  |  |  |  |  |
| 5. This project is a drug clinical trial: Phase \_\_\_\_ |  |  |  |  |  |  |  |
| 6. This project is an observational experiment, instead of an interventional one, and uses such experiment types as medical record retrospect, questionnaire surveys, etc. |  |  |  |  |  |  |  |
| 7.The experiment subject matter of this project is “food/specific nutrient/cosmetic/commodity available for sale through open channels” |  |  |  |  |  |  |  |
| 8. This experiment has collected any biological samples (or already has agreed to a treatment method in the Protocol). |  |  |  |  |  |  |  |
| 9. This experiment does not need approval from the Ministry of Health and Welfare. | --- | --- |  |  |  |  |  |
| 10. This experiment has not appointed CRO for implementation. | --- | --- |  |  |  |  |  |
| 11. The ownership of intellectual property rights is reasonable. | --- | --- |  |  |  |  |  |
| 12.Other matters agreements (1)~(6): |  |  |  |  |  |  |  |
| (1)In case of overpayment, SPONSOR shall coordinate to carry out the refund of overpayment as required by Party A. In respect of residual funds upon termination of Protocol, SPONSOR shall complete the application for refund within one year after closing IRB, in case of overdue application, Institution may not accept the refund application. |  |  |  |  |  |  |  |
| (2)During the execution period of this Protocol, if the Institution needs the assistance of SPONSOR to provide necessary personnel (personnel shall be recruited by SPONSOR or shall be handled by CRO or SMO as appointed by SPONSOR), essential research consumables, drugs and other related items due to research need, SPONSOR shall do its best to cooperate. |  |  |  |  |  |  |  |
| (3) Institution and Principal Investigator agree that SPONSOR, Ethics Committee and regulatory authority may, through prior arrangement, examine relevant materials and facilities during the business hours, SPONSOR shall inform Institution and Principal Investigator one week in advance on the purpose of examination, visitors, specific case in examination and necessary documents, besides, SPONSOR shall comply with the medical record reading regulations of the Institution. |  |  |  |  |  |  |  |
| (4) Market listed instruments and equipment are acceptable to be donated or borrowed by the experiment delegator and shall be numbered by the experiment institute and included in Party A’s fixed asset management. Unlisted instruments and equipment may not be donated or borrowed by the experiment delegator and shall be handled in accordance with the experiment institute’s borrowing rules. Furthermore, the experiment delegator shall be responsible for regular maintenance, repair and expenses in relation to the medicinal materials, as well as for presenting repair records to the experiment institute for review and safekeeping. |  |  |  |  |  |  |  |
| (5)Materials cannot be provided to the Subject for use pursuant to the provisions of laws and regulations and Protocol or due to exceeding the service life; SPONSOR shall recycle them within sixty days after informed by Institution, in case of delay, Institution may send them to SPONSOR through “recipient paid” express delivery, and relevant risks in the course of delivery shall be borne by SPONSOR. |  |  |  |  |  |  |  |
| (6) Implementation costs of the Protocol are specified in the Contract. |  |  |  |  |  |  |  |
| (7) The compensation object in the contract must be consistent with the inform consent. |  |  |  |  |  |  |  |
| \*\*\* Specify subject protection regulations (which shall be examined by medical experts): | | | | | | | |
| 13.Subject protection regulation: |  | | | | | | |
| (1)For potential research-related injury, the arrangements for medical care, including who will provide care and who is responsible to pay for it, should be defined before the research starts. (AAHRPP 1.8 A) |  |  |  |  |  |  |  |
| (2)In studies where Sponsors conduct research site monitoring visits or conduct monitoring activities remotely, the Sponsor should promptly reports to the the IRB and Principal Investigator of the Chang Gung Memorial Hospital any findings that could affect the safety of participants or influence the conduct of the study. (AAHRPP 1.8 B) |  |  |  |  |  |  |  |
| (3)When the Sponsor, or its agents, has the responsibility for data and safety monitoring, the Sponsor should provide the reports from data and safety monitoring to the Principal Investigator who forwards them to the IRB and Principal Investigator of the Chang Gung Memorial Hospital within the time specified by Institution or IRB. (AAHRPP 1.8 C) |  |  |  |  |  |  |  |
| (4) Before initiating research, the Organization has a written agreement with the Sponsor about plans for disseminating findings from the research and the roles that Researchs and Sponsors will play in the publication or disclosure of results. (AAHRPP 1.8 D) |  |  |  |  |  |  |  |
| (5) When findings emerge after a research study within 2 years has ended that directly affect the safety of past participants and were not anticipated at the time the study was designed or conducted, the Sponsor should communicate findings to the IRB and Principal Investigator of the Chang Gung Memorial Hospital by an official letter in order to consider informing participants. (AAHRPP 1.8 E) |  |  |  |  |  |  |  |
| (6)If SPONSOR has authorizes other Clinical Research Organization (CRO) to execute this clinical trials, or SPONSOR has been authorized to execute this clinical trials, SPONSOR shall attach the Power of Attorney of the authorizing CRO. Regarding the final responsibility for maintaining the quality and completeness of the Study data, SPONSOR shall still be held responsible. (JCIA HRP3.1) |  |  |  |  |  |  |  |
| (7)The sponsor ensures that the research data are reliable and valid and the results and reporting are statistically accurate, ethical, and unbiased. (JCIA HRP3) |  |  |  |  |  |  |  |
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| 14. Specify limits of academic publications. |  |  |  |  |  |  |  |
| 15. Specify research achievements allocation and right. |  |  |  |  |  |  |  |
| 16.Specify relevant experiment liabilities for damage, which, except for those intentionally or accidentally caused by the experiment institute or investigators, shall be assumed by the experiment delegator. |  |  |  |  |  |  |  |
| 17. The relevant agreement and compensation for the use of the name have been specified. |  |  |  |  |  |  |  |
| 18. The Contract signatory of the Sponsor is the person in charge of the company, or the Letter of Authorization has been attached (after the manufacturer makes additions and corrections subsequently, it shall be confirmed by the Clinical Trial Center). |  |  |  |  |  |  |  |
| 19.Other: |  |  |  |  |  |  |  |

廠商贊助研究計畫作業準則 A-98 106年05月11日第10次修訂