**Checklist for Clinical Trial Contract**

|  |  |
| --- | --- |
| Protocol Number: |  |
| IRB Number: |  |
| Protocol Title: |  |
| Principal Investigator: |  |
| Sponsor: |  |
| CRO: |  |
| Parties: □Sponsor □CRO | Funding: □Sponsor □CRO □ \_\_\_\_\_\_\_\_\_\_ |

|  | **Review item** | **Sponsor / CRO** | | | **Reviewer** |
| --- | --- | --- | --- | --- | --- |
| **Yes** | **No\*** | **Article No.**  **(\*Reason(s) for the absence of the review item)** | **Review comments** |
|  | **Responsibilities of Principal Investigator, Researchers and Sponsor**  Note 1: Compliance with the Protocol, ICH GCP guidelines, Taiwan GCP, and applicable laws, regulations, and guidelines shall be clearly specified. |  |  |  |  |
| Note 2: The duties and functions delegated by the sponsor to the CRO shall be specified in the clinical trial contract and power of attorney to the CRO should also be provided. The sponsor shall be responsible for the quality and completeness of the trial data. |  |  |  |  |
|  | **Commencement and Duration**  Note: The starting time, end time, and the number of patient to be recruited for the study should be specified. |  |  |  |  |
|  | **Funding**  Note 1: The funding of the trial should be specified in the contract between the sponsor and the Principal Investigator/institution. |  |  |  |  |
| Note 2: According to NCKUH regulations, the NCKUH budget template must be attached to the contract. |  |  |  |  |
| Note 3: Sponsors do not offer any forms (money; valuable materials) of referral fee or bonus payment for the incentive of accelerating the recruitment of subjects.  **(See Element II.3.C. of the AAHRPP)** |  |  |  |  |
|  | **Confidentiality**  Note: The scope and the time period of confidentiality (should be no more than 10 years) should be specified. |  |  |  |  |
|  | **Intellectual Property Rights**  Note: The owner(s) of the research results should be specified. |  |  |  |  |
|  | **Institutional Review Board**  Note: The fact that the trial shall be conducted in accordance with the protocol already approved/agreed by the Institutional Review Board (IRB) should be specified. |  |  |  |  |
|  | **Data Protection and Financial Disclosure**  Note: The confidential record which may identify the subject shall be protected, and sponsor should also comply with the privacy and confidentiality requirements under related laws and regulations. |  |  |  |  |
|  | **Informed Consent Form and Recruitment of Subjects**  Note: Each subject shall sign the informed consent form voluntarily prior to the clinical trial. |  |  |  |  |
|  | **Trial Information , Biological Samples and Trial Record**  Note: All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification, and shall comply with related requirements. |  |  |  |  |
|  | **Monitoring**  Note 1: The sponsors are required to promptly (no longer than within 30 days) report to NCKUH IRB findings that could (1) affect the safety and welfare of participants, (2) influence the conduct of the study, (3) affect the willingness of participants to continue participation in the study, or (4) alter the IRB’s approval to continue the study during the clinical trial monitoring process. (***See Element I.8.B. of the AAHRPP***) |  |  |  |  |
| Note 2: When the sponsor or its agent has the responsibility to conduct data and safety monitoring, the sponsor shall provide the data and safety monitoring plans to the Principal Investigator and NCKUH IRB. Meanwhile, it shall explain and provide the time frame for submission of routine and urgent reports. (***See Element I.8.C. of the AAHRPP***) |  |  |  |  |
|  | **Publications**  Note 1: The right of both parties’ authority to publish the research results should be specified. (***See Element I.8.D. of the AAHRPP***) |  |  |  |  |
| Note 2: Principal Investigator and Institution have the rights to publish the research results for academic use under the following conditions. |  |  |  |  |
| (1) Institution shall provide sponsor with a copy of the papers (manuscript, poster abstract, lecture or oral presentation) at least 60 days prior to their submission to a scientific journal or presentation at scientific meetings. |  |  |  |  |
| (2) If identified by Sponsor, any Sponsor Confidential Information that may be contained therein shall be deleted. |  |  |  |  |
| (3) 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 2 years of completion or termination of Study at all participating sites, Institution is free to publish separately. |  |  |  |  |
|  | **Indemnity and Insurance**  Note 1: For potential study-related injury, sponsors are required to indicate the arrangements for medical care before the trial begins, including who will provide care and who is responsible to pay for it.  (***See Element I.8.A. of the AAHRPP***) |  |  |  |  |
| Note 2: Unless the injury can be attributed to the institution or Principal Investigator, the sponsor shall be responsible for the damages caused by the trial. |  |  |  |  |
|  | **Termination**  Note 1: When the sponsor finds any information which is unexpected and could directly affect the subject’s safety, a time frame\* after closure of the study during which the sponsor will communicate such findings to the Principal Investigator and NCKUH in order to inform participants should be specified. The method to notify shall be expressly stated in the contract or related documents.[\*time frame: usually two years after the study has ended]  (***See Element I.8.E. of the AAHRPP***)**.** |  |  |  |  |
| Note 2: Termination of the contract shall also take the subject’s interest and right into consideration. |  |  |  |  |
|  | **Use of Name**  Note: Without prior written consent from NCKUH, the name of NCKUH may not be used for commercial purposes or any publicity. If Sponsor violates this clause, shall state the clarification via the same platform or medium or NCKUH specified medium. If the violation causes any damages to the reputation or rights and interests of NCKUH, Sponsor shall be liable for the damage compensation. NCKUH may suspend the process of Sponsor's new clinical trial applications for 1-3 year(s), depending on the circumstances of the violation. |  |  |  |  |
|  | **Applicable Law and Jurisdiction**  Note 1: The clinical trial contract shall be signed in both Mandarin and English versions. In the case of discrepancy in the two versions, the Mandarin version shall apply. |  |  |  |  |
| Note 2: The court of competent jurisdiction shall refer to the court situated in the jurisdiction where the institution is located. |  |  |  |  |
|  | **Other** |  |  |  |  |

Reviewer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_