**臺大醫院臨床試驗/研究新案合約簽署檢核表**(checklist 1)

**Checklist 1: New Clinical Trial Contract Signing Checklist**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 計畫名稱： | | | | | |
| 計畫主持人/科部： | | | IRB編號： | | |
| **申請資料請依下表順序置放：** | | | | | |
| No. | **項目** | | | **備齊(V)** | **醫研部確認(V)** |
| 1 | 計畫主持人簽陳（**計畫主持人**與**部主任**需核章） | | | V |  |
| 2 | 新案合約書簽署檢核表(Checklist 1, 2, 3) | | | V |  |
| 3 | 臺大醫院研究倫理委員會核准公文/許可書 | | | V |  |
| 4 | 衛生福利部許可公文（若不須檢附請選NA並於簽陳敘明原因） | | | **請選擇** |  |
| 5 | 計畫書 | | | V |  |
| 6 | 合約書1式3份（若須3份以上請於簽陳內文說明）   * 每份均需包含**本院格式之經費表**（含經費總預算表、付款時間表及繳納方式、支付明細表） * 計畫主持人、委託/贊助者須先簽署 * 用印處正確標示本院及代表人姓名/職稱：   　　請依實際合約格式自行填寫以下資訊  　　中文：國立臺灣大學醫學院附設醫院，吳明賢院長  　　英文：Professor Ming-Shiang Wu, Superintendent,  　　　　　National Taiwan University Hospital | | | V |  |
| 7 | 藥品管理費評估表（經藥師核章確認，不適用請選NA） | | | **請選擇** |  |
| 8 | 受託研究機構(CRO)委託書/授權書（無委託CRO者不適用請選NA） | | | **請選擇** |  |
| 9 | 臨床試驗委託案前置準備行政作業費繳費單第一聯**正本**及收據**影本**  （非廠商委託計畫不適用請選NA） | | | **請選擇** |  |
| 10 | 單獨一份本院格式之經費表，含經費總預算表、付款時間表及繳納方式、支付明細表（無經費贊助請選NA） | | | **請選擇** |  |
| **委託/贊助者：** | | **送件人：** | | **職稱：** | |
| **紙本送件日期：** | | **電話：** | | **Email：** | |
| **醫研部收件人簽章/日期：** □ 文件不足，請補件 □ 送件資料無誤 | | | | | |

**檢核表2:受試者保護事項檢核表**

**Checklist 2: Human Subjects Protection Checklist**

臨床試驗計畫合約書應視情形明定下列事項：

When appropriate, the following items should be included in the clinical trial contract:

* 1. **如臨床試驗有造成受試者傷害之虞者，試驗委託者應於試驗開始前敘明其醫療安排，包括醫療提供者及支付費用者**

**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 I.8.A).**

是，訂於合約書中第 頁，第 條，或其他合約文件：

Yes, in the contract, set forth on page ,article ; or other contractual documents

否，請說明：

No, please specify

* 1. **如試驗委託者執行臨床試驗之監測，發現對受試者有安全疑慮及影響臨床試驗之執行時，應立即通報臺大醫院研究倫理委員會及受試者保護中心**

**In studies where Sponsors conduct research site monitoring visits or conduct monitoring activities remotely, the Sponsor should promptly reports to the National Taiwan University Hospital IRB and Human Research Protection Center any findings that could affect the safety of participants or influence the conduct of the study (AAHRPP I.8.B).**

是，訂於合約書中第 頁，第 條，或其他合約文件：

Yes, in the contract, set forth on page ,article ; or other contractual documents

否，請說明：

No, please specify

* 1. **試驗委託者或其代理人負責臨床試驗之資料與安全監測時，應提供安全監測報告給計畫主持人及臺大醫院研究倫理委員會，並說明提供例行報告及緊急報告之時程**

**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 or EC. The time frame for providing routine and urgent data and safety monitoring reports should be specified (AAHRPP I.8.C).**

是，訂於合約書中第 頁第 條，或其他合約文件：

Yes, in the contract, set forth on page ,article ; or other contractual documents

否，請說明：

No, please specify

* 1. **試驗委託者於臨床試驗結束後（例如結案後2年內），如發現有非預期且直接影響受試者安全之資訊，應通知計畫主持人及臺大醫院（研究倫理委員會），以利後者考慮是否需轉告受試者。通知之具體方式應明定於合約書中或相關文件**

**When findings emerge after a research study 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 Researcher and the National Taiwan University Hospital (Research Ethics Committee) in order to consider informing participants. The steps and the time frame (usually two years** **after a research study has ended) followed to communicate findings should be specified (AAHRPP I.8.E)**

是，訂於合約書中第 頁第 條，或其他合約文件：

Yes, in the contract, set forth on page ,article ; or other contractual documents

否，請說明：

No, please specify

* 1. **試驗委託者轉移給受託研究機構(CRO)的職責與功能，應明訂於臨床試驗合約書(JCI HRP.3.1)；受託研究機構必須遵守民法有關居間及行紀之規定，若違反規定時，需擔負損害賠償責任（民法567條：居間人關於訂約事項，應就其所知，據實報告於各當事人。對於顯無履行能力之人，或知其無訂立該約能力之人，不得為其媒介。以居間為營業者，關於訂約事項及當事人之履行能力或訂立該約之能力，有調查之義務）。**

**The duties and functions transferred by the sponsor to the contract research organization are specified in a written contract (JCI HRP.3.1); the contract research organization must comply the provisions of the Civil Code of the Republic of China related to “Brokerage” and “Commission Agency”, in the event of a violation, the contract research organization shall be liable for damages. (The broker is bound to truthfully report to each party the circumstances of the proposed transaction, so far as the broker knows them. The broker shall not act as an intermediary for a person who is clearly insolvent or whom the broker knows to have no capacity to enter into the proposed contract. A business broker has a duty to investigate the circumstances of the proposed transaction and the solvency or capacity of each party to enter into the proposed contract (Article 567 of the Civil Code of the Republic of China).**

是，訂於合約書中第 頁第 條，或其他合約文件：

Yes, in the contract, set forth on page ,article ; or other contractual documents

否，本計畫無受託研究機構

No, this study does not involve a contract research organization (CRO).

1. **試驗藥品應送臺大醫院臨床試驗藥局管理**

**Investigational drugs should be sent to the National Taiwan University Hospital’s Investigational Drug Pharmacy for management and dispensing.**

**依藥品優良臨床試驗作業準則，試驗藥品之管理應由專責藥師辦理**

**According to the "Regulations for Good Clinical Practice," the management of investigational drugs should be handled by a designated pharmacist.**

是，訂於合約書中第 頁第 條，或其他合約文件：

Yes, in the contract, set forth on page ,article ; or other contractual documents

否，請說明：

No, please specify

**注意：委託者對上述項目勾填「是」者，視為所勾填之項目均符合相關AAHRPP評鑑基準、JCI評鑑基準及法令規定。如約款有不明確之處，委託者同意以上述規定做為補充約款。**

**Note:** Whenthe SPONSOR checks “YES” for the above items, it shall be deemed that the Clinical Trial Agreement complies with the relevant AAHRPP standards, JCI standards, and applicable regulations. If there is any ambiguity or uncertainty in the agreement, **the SPONSOR agrees that the above requirements will serve as supplement provisions or will override the relevant terms in the agreement.**

**檢核表3:合約條款檢核表**

**Checklist 3-Contract Clause Checklist**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| No. | 項目(items) | 頁碼  (page) | 條文編號  (clause number) | 醫研部  確認(V) |
|  | Responsibility of Investigators and Research Staff |  |  |  |
|  | Responsibility of Sponsor |  |  |  |
|  | Funding |  |  |  |
|  | Protocol |  |  |  |
|  | Study Conduct |  |  |  |
|  | Independent Ethics Committee or Institutional Review Board |  |  |  |
|  | Data Protection and FDA Financial Disclosure |  |  |  |
|  | Informed Consent and Subject Recruitment |  |  |  |
|  | Adverse Events |  |  |  |
|  | Investigational Drug/Medical Device |  |  |  |
|  | Study Data, Biological Samples, and Study Records |  |  |  |
|  | Monitoring, Inspections, and Audits |  |  |  |
|  | Publications |  |  |  |
|  | Indemnification |  |  |  |
|  | Conflict with Attachments |  |  |  |
|  | Termination |  |  |  |
|  | Sponsor’s Anti-Corruption Policy |  |  |  |
|  | Use of Name |  |  |  |

\* 不適用請填NA (Please fill in “NA” if not applicable)

**紙本送件時本頁以下請勿印出**

**檢核表2&3填表說明(Guidelines for completing the checklist 2 and checklist 3)**

**Checklist 2-** **Protection of Human Subjects Checklist**

1. **AAHRPP I.8.A. Sample Language:**

[The sponsor] will provide payment to the institution for reasonable, unreimbursed medical expenses, including hospitalization, which the institution may incur as a direct result of the treatment of a participant’s injuries that directly result from the study drug or its administration during the clinical trial, as determined by [the sponsor] and the principal investigator.

Research-Related Injury. [The sponsor] shall be responsible for payment of the actual and reasonable medical expenses incurred in diagnosing and treating any injury, illness, or adverse reaction of a study participant that results from the administration of the study drug [or device] in accordance with the protocol or the proper performance of any Protocol procedure.

1. **AAHRPP 1.8.B. Sample Language:**

[The sponsor] or CRO conducts monitoring of sites on a periodic basis throughout the study. If a monitor finds non-compliance at the site that affects safety or materially affects the proper conduct of the study, [the sponsor] or CRO shall in a timely manner notify the investigator, and if non-compliance is serious or continuing, the site.

The following is acceptable language for I.8.B., I.8.C., and I.8.E. because it is written to cover all:

During and for a period of [specify a period of time appropriate to the specific study, for example, at least two years after the completion of the study; or specify a triggering event, for example, completion of data analysis], [the sponsor] shall promptly (or in a timely manner appropriate to the level of risk involved) report to the investigator any information that could directly affect the health or safety of past or current study participants or influence the conduct of the study, including but not limited to the study results and information in site monitoring reports and data safety monitoring committee reports as required by the protocol. In each case, the investigator and [the organization] shall be free to communicate these findings to each study participant and the IRB.

1. **AAHRPP 1.8.C. Sample Language:**

[The sponsor] shall promptly notify investigator of any findings of (1) new and unexpected serious adverse safety events arising from [the sponsor’s] monitoring of the study that could affect the safety of participants, and (2) trends or patterns of non-serious or expected adverse events that occur at a specificity or severity that is inconsistent with prior observations, all in accordance with the obligations set forth in 21 C.F.R. 312.32(c), 21 C.F.R. 312.55(b), 21 C.F.R. 56.108(b) and FDA's Guidance on Adverse Event Reporting to Institutional Review Boards in Clinical Trials (January 2009). [The sponsor] agrees to provide data and safety monitoring plans to the principal investigator prior to IRB review of the study.

[The sponsor] will provide the [organization’s] principal investigator with any findings from its data and safety monitoring that could affect the safety of participants or their willingness to participate or influence the conduct of the study. Reports of an urgent nature must be provided within ten business days; routine reports must be submitted within 30 business days. (This language is not required in the contract if these provisions are described in the protocol).

The following is acceptable language for I.8.B. and I.8.C. because it is written broadly enough to cover both:

[The sponsor] shall provide notice to the institution of any findings that may (i) affect the safety and welfare of participants, (ii) affect the willingness of participants to continue their participation in the clinical trial, (iii) influence the conduct of the clinical trial, or (iv) alter the IRB's approval to continue the clinical trial. The institution will work with its IRB and the principal investigator to disseminate this information to the participants.

1. **AAHRPP 1.8.E. Sample Language:**

Following completion of this study under this contract, if [the sponsor] becomes aware of relevant findings from the study data that would directly affect the safety of the former study participants, [the sponsor] shall promptly (or in a timely manner appropriate to the level of risk) notify the institution of such relevant finding so that the institution may communicate such findings to the former study participants. [The sponsor] shall determine the relevance of the findings and the institution shall inform former study participant as appropriate. [The sponsor’s] reporting obligation shall continue for two years following completion of the study conducted under this contract or until the occurrence of a triggering event (such as a data lock).

The following is acceptable language for I.8.B., I.8.C., and I.8.E. because it is written to cover all:

During and for a period of at [specify a period of time appropriate to the specific study, for example, least two years; or specify a triggering event, for example, completion of data analysis] after the completion of the study, [the sponsor] shall promptly (or in a timely manner appropriate to the level of risk) report to the investigator any information that could directly affect the health or safety of past or current study participants or influence the conduct of the study, including but not limited to the study results and information in site monitoring reports and data safety monitoring committee reports as required by the protocol. In each case, the investigator and [the organization] shall be free to communicate these findings to each study participant and the IRB.

1. **The duties of contract research organization (CRO)**

In the event adequate funds are not made available by Sponsor for payment hereunder in accordance with payment term, CRO shall attempt to negotiate with Sponsor and is obligated to promptly notify the Institution and Investigator to suspend the study activities until the funding issue is resolved. If the funding issue cannot be resolved, all parties agree to discuss in good faith the relevant matters regarding the suspension of the Study. If CRO fails to comply with the notification obligation and causes damage to the Institution and/or Investigator, CRO shall be liable for compensation for the damages.

如遇試驗委託者無法依據本合約所訂之付款條件支付款項，受託研究機構應盡可能與試驗委託者交涉，並有義務及時通知機構及計畫主持人暫停試驗；若經費問題無法獲得解決，雙方同意秉持善意原則商討中止本試驗之相關事宜；若受託研究機構違反通知義務而造成機構及/或計畫主持人損害，受託研究機構應擔負損害賠償責任。

**Checklist 3-** **Agreement Clause Checklist**

**1. Responsibility of Investigators and Research Staff**

* 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 E6 4.1.1)
* The investigator should be thoroughly familiar with the appropriate use of the investigational product(s), as 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)
* The investigator should be aware of, and should comply with, GCP and the applicable regulatory requirements. (ICH E6 4.1.3)
* The investigator/institution should permit monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authority(ies). (ICH E6 4.1.4)
* The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties. (ICH E6 4.1.5)

**2. Responsibility of Sponsor**

* The 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). (ICH E6 5.1.1)
* The sponsor is responsible for securing agreement from all involved parties to ensure direct access (see 1.21) to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor, and inspection by domestic and foreign regulatory authorities. (ICH E6 5.1.2)
* Quality control should be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly. (ICH E6 5.1.3)
* Agreements, made by the sponsor with the investigator/institution and any other parties involved with the clinical trial, should be in writing, as part of the protocol or in a separate agreement. (ICH E6 5.1.4)

**3. Funding**

* The financial aspects of the trial should be documented in an agreement between the sponsor and the investigator/institution. (ICH E6 5.9)
* 臨床試驗之財務計畫，應由試驗委託者和試驗機構或試驗主持人訂定書面契約（藥品優良臨床試驗作業準則第102條）。
* 臨床試驗所有經費皆入醫院公庫帳戶（依據本院「學術研究支援專款管理要點」）。
* 本臨床試驗相關經費，應全部編列於本合約中。締約之一方不得要求或接受他方另行提供臨床試驗合約書以外之經費或具財物價值之品項給予締約之當事人或其指定之人。
* 如遇試驗委託者無法依據本合約經費表支付款項，受託研究機構應盡可能與試驗委託者交涉，並有義務及時通知機構及計畫主持人暫停試驗；若經費問題無法獲得解決，雙方同意秉持善意原則商討中止本試驗之相關事宜；若受託研究機構違反通知義務而造成機構及/或計畫主持人損害，受託研究機構應擔負損害賠償責任。

In the event adequate funds are not made available by SPONSOR for payment hereunder in accordance with the Budget Plan, CRO shall attempt to negotiate with SPONSOR and is obligated to promptly notify the Institution and Investigator to suspend the study activities until the funding issue is resolved. If the funding issue cannot be resolved, all parties agree to discuss in good faith the relevant matters regarding the suspension of the study. If CRO fails to comply with the notification obligation and causes damage to the Institution and/or Investigator, CRO shall be liable for compensation for the damages.

**4. Protocol**

* The contents of a trial protocol should generally include the 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)

**5. Study Conduct**

* Systems with procedures that assure the quality of every aspect of the trial should be implemented. (ICH E6 2.13)

**6. Independent Ethics Committee or Institutional Review Board**

* A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favourable opinion. (ICH E6 2.6)

**7. Data Protection and FDA Financial Disclosure**

* 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)

**8. Informed Consent and Subject Recruitment**

* Freely given informed consent should be obtained from every subject prior to clinical trial participation. (ICH E6 2.9)

**9. Adverse Events**

* 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)
* 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)
* 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 all adverse drug reactions (ADRs) that are both serious and unexpected. (ICH E6 5.17.1)

**10. Investigational Drug**

* 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)

**11. Study Data, Biological Samples, and Study Records**

* 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)

**12. Monitoring, Inspections, and Audits**

* 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)

**13. Publications**

* Principle：

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.  Institution shall provide sponsor with a copy of the papers (manuscript, poster abstract, lecture or oral presentation) at least thirty (30) days prior to their submission to a scientific journal or presentation at scientific meetings.  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 Confidential Information that may be contained therein shall be deleted.

Multi-Center Studies. 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.

**AAHRPP 1.8.D. Sample Language:**

[The sponsor] acknowledges and accepts the interest of the [organization] in the non-commercial publication of the results, independent of a positive or negative outcome of the study. With respect to any proposed publication or presentation of the results of the study, the organization and/or investigator agree to submit to [the sponsor] a copy of the proposed publication or presentation at least two months prior to the submission thereof for publication or the date of such presentation in order to allow [the sponsor] to review it. Any manuscript for publication submitted to [the sponsor] shall be reviewed without unreasonable delay, and approval shall not be withheld unreasonably. If [the sponsor] does not notify [the organization] within thirty (30) days of the [the sponsor’s] receipt of the intended publication, [the organization] shall be free to publish. In the case a difference of opinion between [the sponsor] and [the organization], the contents of the publication will be discussed in order to find a solution which satisfies both parties. [The organization] acknowledges that in the case of multi-center studies the results of the study are to be published only through coordination by [the sponsor] in order to combine the results of all participating centers. [The organization] shall be free to publish the results of their center provided the overall results have not been published with twenty-four (24) months from the completion of the study, subject to the compliance to the remaining terms set forth in the section. [The sponsor] may recommend any changes to the publication it reasonably believes are necessary for scientific purposes. [The organization] agrees that the implementation of such recommended changes shall not be unreasonably refused. If [the sponsor] informs [the organization] that such publication could be expected to have an adverse effect on the confidentiality of any of [the sponsor’s] confidential information, [the organization] shall prevent the publication, unless the confidential information can be deleted from the publication without detriment effect on the scientific correctness of the publication. If the publication could in [the sponsor’s] view have an adverse effect on the ability to obtain patent protection for any invention, [the sponsor] may request a delay of the publication for a reasonable period of time in order to permit the preparation and filing of any desired patent application by or on behalf of [the sponsor], such period, however, not to exceed three months from the date on which [the sponsor] received the intended publication for review. [The sponsor] may request a further delay of publication only in the case when a patent application has been filed and the prior application is incomplete and subject matter has to be added to the application during the priority year. In this case [the sponsor] may request delay of any publication until the competition of the priority application. [The sponsor] shall not unduly delay such completion. [The organization] and/or investigator shall comply with all applicable requirements regarding disclosure of industry support (financial or otherwise) in connection with such publications and presentations. [The organization] shall impose the same obligations on publication as set forth in this section on all study team members. The obligation set forth in this section shall survive for a period of ten (10) years upon early termination or expiration of this Agreement.

Publication. [The organization] shall be free to use the results of the research and clinical study for its own teaching, research, education, clinical and publication purposes without the payment of royalties or other fees. [The organization] shall submit to [the sponsor] for its review, a copy of any proposed publication resulting from the research at least thirty (30) days prior to the date of submission for publication, and shall consider in good faith all comments provided by [the sponsor] during that review period. If [the sponsor] determines that the proposed publication contains patentable subject matter which requires protection, [the sponsor] may require the delay of publication for a period of time not to exceed sixty (60) days for the purpose of filing patent applications. {If multicenter study, may insert language agreeing to delay publication until the earlier of the multicenter publication, or one year after end of study, but with firm commitment from Sponsor to encourage publication}.

中文範例條款：

機構及計畫主持人可自行發表其在執行試驗調查所發現的結果。凡由其提出的報告作者排名與內容（包括科學結論與專業判斷）皆應由機構及計畫主持人決定。唯機構或計畫主持人在提出準備供其本身或供協同主持人發表的文章之前，若為向學術專刊或在學術會議提出者，得於預定發表日期前，儘早將該文稿複本一份提交試驗委託者/贊助者；若為任何其他口頭或書面發表者，得於預定提出或發表日期前，將一份詳細的摘要或摘要說明儘早（最少三十日前）提交試驗委託者/贊助者。試驗委託者/贊助者可就發表指出的結果及結論向機構或計畫主持人或協同主持人提出意見，唯不得對發表內容做出任何更改。若經試驗委託者/贊助者識別出其中可能含有試驗委託者/贊助者的機密訊息者，機構及計畫主持人須將以刪除。凡依本條款說明的各種發表中，得依一般學術模式，對試驗委託者/贊助者人員提出感謝的聲明。

**14. Indemnification**

* 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)
* The sponsor's policies and 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)
* When trial subjects receive compensation, the method and manner of compensation should comply with applicable regulatory requirement(s). (ICH E6 5.8.3)

**15. Conflict with Attachments**

* The investigator/institution and the sponsor should sign the protocol, or an alternative contract, to confirm agreement. (ICH E6 4.5.1)
* The Protocol, including any amendments thereto, constitutes an integral part of this Agreement by reference. In case of any inconsistency between this Agreement and the Protocol, the Protocol shall take precedence on matters of medicine, science and conduct of the Study; otherwise the terms of this Agreement shall prevail.

**16. Termination**

* If the trial is prematurely terminated or suspended for any reason, the investigator/institution should promptly inform the trial subjects, 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 4.12)
* 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 5.21)

**17. SPONSOR’s Anti-Corruption Policy**

* SPONSOR’s corporate policies provide that SPONSOR colleagues must conduct all SPONSOR business in a lawful and ethical manner, in accordance with applicable laws and regulations, including the U.S. Foreign Corrupt Practices Act of 1977 (the “FCPA”). The FCPA prohibits making, promising, or authorizing the making of a corrupt payment or providing anything of value to a government official to induce that official to make any governmental act or decision to assist a company in obtaining or retaining business. The FCPA also prohibits a company or person from using another company or individual to engage in any of the foregoing activities. As a U.S. company, SPONSOR must comply with the FCPA and as such, requires that its consultants, agents, representatives, and a company’s acting on its behalf (“Business Associates”) do the same. Consequently, SPONSOR requires all of its Business Associates to conduct themselves in accordance with these principles.
* Business Associates may not directly or indirectly make, promise, or authorize the making of a corrupt payment or provide anything of value to any government official to induce that government official to make any governmental act or decision to help SPONSOR obtain or retain business. Business Associates may never make a payment to or offer a government official any item or benefit, regardless of value, as an improper inducement for such government official to approve, reimburse, prescribe, or purchase a SPONSOR product, to influence the outcome of a clinical trial, or otherwise improperly to benefit SPONSOR’s business activities.
* 本合約任一方（包含其代表人、員工或所有相關人員）保證並擔負以下責任：
  + 未曾亦將不會，直接或間接提供、承諾、支付（或授權此等提供或支付）政府官員、健康照護專業人員、任何其他人士任何金錢或給予任何有價物，或者為了對上開人員施加不當影響力之目的而採取任何行動。
  + 未曾亦將不會接受、要求或接收任何可能不當影響各方依據本合約執行業務之金錢或任何有價物。

**18. Use of Name**

* Neither party will use the name of the other party or any of its employees for promotional or advertising purposes without written permission from the other party.
* 名稱之使用

除法律及法規之要求，任何一方於廣告、行銷，或提供資料給媒體（含引用研究報告），或接受媒體採訪時，未經他方事先書面同意，不得使用他方名稱、標識、商標、實體肖像、員工名稱、擁有人之表徵或其他圖像。違反前項約定者，如造成他方名譽或其他權益受損，亦應賠償。