抄本

國立臺灣大學醫學院附設醫院　函

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密等及解密條件或保密期限：
附件：30800-2-000068_ 臨床試驗暨臨床研究合約簽署辦法_20240611

主旨：公告本院新制定「臨床試驗暨臨床研究合約簽署辦法」，並自即日起實施，敬請查照並轉知所屬。

說明：

一、依據本院113年6月11日第87次臨床研究管理委員會決議及奉113年6月20日院長核定辦理。

二、為辦理本院臨床試驗暨臨床研究合約簽署業務，及統整現行合約簽署之各項規定及作業程序，特制定「臨床試驗暨臨床研究合約簽署辦法」，並自公告日起實施，另廢止現行「臨床試驗合約簽署須知」。

三、相關表單一併更新，請至本院臨床試驗中心網站查閱及下載https://www.ntuh.gov.tw/NCTRC/Fpage.action?muid=4434&fid=4636。

正本：中華民國開發性製藥研究協會、台灣藥物臨床研究協會、全院同仁-全院公告
副本：藥品臨床試驗合約副本收文者、記帳扣款業務副本收文者、全院各醫療單位登記桌（均含附件）

文件名稱	臨床試驗暨臨床研究合約簽署辦法		權責單位	醫學研究部	頁碼/總頁數	1/21
文件編號	30800-2-000068	版次	1	修制訂日期	2024/06/11	
				檢視日期	2024/06/11	
				公告日期	2024/06/24	

2024 年 6 月 11 日第 87 次臨床研究管理委員會議通過並於 6 月 20 日奉院長核定

一、國立臺灣大學醫學院附設醫院（下稱本院）依據 ICH GCP 4.5.1、藥品優良臨床試驗作業準則第 89 條及相關規定，辦理臨床試驗暨臨床研究合約簽署業務，特制定臨床試驗暨臨床研究合約簽署辦法（下稱本辦法），以規範合約簽署之作業程序。

二、適用範圍：

（一）本院外部之公私立機構委託之臨床試驗或臨床研究計畫案，本院研究者自行發起有外部機構部分贊助研究資源之計畫案，及本院自行發起與院外單位共同執行之多中心臨床試驗或臨床研究計畫案。

（二）前項所稱之臨床試驗或臨床研究計畫案（以下簡稱計畫案），依據本院研究倫理委員會規定，包含新案、變更案、終止案、受聘擔任臨床試驗諮詢委員或其他案件。

三、研究計畫審定：本辦法第二項所列之計畫案，必須經過本院研究倫理委員會審定核准，如屬須經主管機關核准之案件，則應取得主管機關之核准。

四、合約文件標準：

（一）合約文件可由委託方、贊助方或合作機構提供，或前述各方同意由本院提供。

（二）合約內容必須符合本院檢核表（附件一）所訂之必備內容，及符合美國人體研究保護計畫認證協會（Association for Accreditation of Human Research Protection Programs, AAHRPP）訂定之評鑑規範。

（三）除委託計畫案之外，研究成果（包含且不限於試驗資料、數據、研究報告、專利、發明等智慧財產權）歸屬於本院或與合作機構共有，如有例外，須經臨床研究管理委員會核准後方可同意簽約。

五、計畫案經費編列及管理

（一）計畫案經費之編列須依據本院提供之臨床試驗經費總預算內容及格式（附件二）。

（二）計畫案經費皆須存入本院「台大醫院作業基金 401 專戶」，並依本院學術研究支援專款管理要點編列統籌發展費。

六、簽約方式

（一）由委託方、贊助方或合作機構之代表人，與本院代表人（院長）及計畫主持人簽署三方合約；本院自行發起與院外單位共同執行之多中心臨床試驗或臨床研究計畫案須納入合作機構之計畫主持人簽署四方合約。

（二）前述委託方如委託受託研究機構代表簽約，需提出委託方之書面委託文件。

（三）計畫主持人若為本院兼任人員，需有專任於本院之協同主持人共同簽署。

七、簽約申請方式

（一）計畫主持人於計畫案送研究倫理委員會審查期間，可同步將合約文件送至醫學研究部所屬臨床試驗中心提出預審申請。

（二）醫學研究部所屬臨床試驗中心收到完整審查申請資料後，承辦人員於二週內向計畫主持人回覆審查意見，計畫主持人應依據審查意見進行修改及回覆，所有文件內容審查通過後，承辦人員通知計畫主持人進行簽署用印行政程序（附件三）。

（三）廠商委託之計畫案須於合約簽署前繳納前置準備行政作業費。

八、本辦法若有未盡事宜，依相關法律及本院規定辦理。

九、本辦法經本院臨床研究管理委員會通過並奉院長核定後實施。

附件一、檢核表

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）		
2	申請臺大醫院簽署臨床試驗/臨床研究新案合約書簽署檢核表 (Checklist 1, 2, 3)		
3	臺大醫院研究倫理委員會核准公文及許可書		
4	衛生福利部許可公文（若不須檢附需於簽陳敘明原因）		
5	計畫書		
6	合約書 1 式 3 份[a] ● 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		
7	藥品管理費評估表（經藥師核章確認）		
8	受託研究機構(CRO)委託書/授權書（無委託 CRO 者不適用）		
9	臨床試驗委託案前置準備行政作業費繳費單影本及收據第一聯正本（非廠商委託計畫不適用）		
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）		

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

[a]若須 3 份以上請於簽陳內文說明

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:

A. 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，已有約定於合約書中第___頁第___條，或其他合約文件：_____

Yes, Already agreed upon and cited on page __ and line __ in the contract; or other contract documents: _____

☐ 否，請說明：_____

No, Please comment:_____

B. 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，已有約定於合約書中第___頁第___條，或其他合約文件：_____

Yes, Already agreed upon and cited on page __ and line __ in the contract; or other contract documents: _____

☐ 否，請說明：_____

No, Please comment:_____

C. 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，已有約定於合約書中第___頁第___條，或其他合約文件：_____

Yes, Already agreed upon and cited on page __ and line __ in the contract; or other contract documents: _____

☐ 否，請說明：_____

No, Please comment:_____

D. 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，已有約定於合約書中第___頁第___條，或其他合約文件：_____

Yes, Already agreed upon and cited on page __ and line __ in the contract; or other contract documents: _____

☐ 否，請說明：_____

No, Please comment:_____

E. 試驗委託者轉移給 CRO 的職責與功能，應明訂於臨床試驗合約書

The duties and functions transferred by the sponsor to the contract research organization are specified in a written contract (JCI HRP.3.1).

☐ 是，已有約定於合約書中第___頁第___條，或其他合約文件：_____

Yes, Already agreed upon and cited on page __ and line __ in the contract; or other contract documents: _____

☐ 否，請說明：_____

No, Please comment:_____

F. 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，已有約定於合約書中第___頁第___條，或其他合約文件：_____

Yes, Already agreed upon and cited on page __ and line __ in the contract; or other contract documents: _____

☐ 否，請說明：_____

No, Please comment:_____

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: When the SPONSOR checks "YES" in the above items, it will be deemed that the Clinical Trial Agreement is in accordance with relevant requirements of AAHRPP standards, JCI standards or regulations. If there is uncertainty of whether the agreement is consistent with the above requirements, **the SPONSOR agrees that the above requirements will supplement or override the relevant stipulations 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)	備齊 (V)	醫研部確認(V)
1.	Responsibility of Investigators and Research Staff.				
2.	Responsibility of Sponsor				
3.	Funding				
4.	Protocol				
5.	Study Conduct				
6.	Independent Ethics Committee or Institutional Review Board				
7.	Data Protection and FDA Financial Disclosure				
8.	Informed Consent and Subject Recruitment				
9.	Adverse Events				
10.	Investigational Drug/Medical Device				
11.	Study Data, Biological Samples, and Study Records				
12.	Monitoring, Inspections, and Audits				
13.	Publications				
14.	Indemnification				
15.	Conflict with Attachments				
16.	Termination				
17.	Sponsor's Anti-Corruption Policy				
18.	Use of Name				

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.

2. **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.

3. **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.

4. **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.

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。

臺大醫院臨床試驗合約變更案簽署檢核表

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：			
	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） ● 說明變更理由 ● 詳列變更內容		
2	臺大醫院研究倫理委員會許可函（變更需經研究倫理委員會審查者）		
3	衛生福利部許可公文（變更需報部核准之試驗計畫類別者）		
4	合約書 1 式 3 份 [a] ● 若經費變更者請附上最新版**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		
5	臨床試驗計畫摘要		
6	歷次合約發文函、合約書影本		
7	新舊合約書變更對照表（請下載範本）		
8	臨床試驗經費明細修改對照表（請下載範本）		

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

[a] 若需 3 份以上請於簽陳內文說明

臺大醫院臨床試驗合約終止案簽署檢核表

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：			
	項目	備齊(V)	收件確認(V)
1	計畫主持人簽陳（計畫主持人與部主任需核章） ● 說明終止日期 ● 臨床試驗之狀況 ● 終止原因 ● 已收案受試者之後續處理 ● 臨床試驗委託者未收案前終止臨床試驗案，廠商依已簽署之臨床試驗合約規定支付臨床試驗終止後續費用(新案合約於2022/3/1 之後送預審者不適用)		
2	臺大醫院研究倫理委員會臨床試驗計畫終止核備公文		
3	衛生福利部試驗計畫終止核備公文		
4	終止臨床試驗計畫合約書 1 式 3 份 [a] ● 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/執稱： 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		
5	歷次合約發文函、合約書影本		
委託/贊助者：	**送件人：**	**職稱：**	
紙本送件日期：	**Tel：**	**Email：**	
醫研部收件人簽章/日期： _____ ☐ 文件不足，請補件 ☐ 送件資料無誤			

[a] 若須 3 份以上請於簽陳內文說明

臺大醫院人員受聘擔任臨床試驗諮詢委員合約檢核表

申請人姓名/科部：

受聘類別：☐ Clinical Trial Committee Member ☐ Study Chairman
☐ Consultant ☐ Other _____

聘任機構：

計畫名稱：

IRB 編號：

請依下列表單順序置放，並勾選您已檢附之申請表格：

	項目	備齊(V)	醫研部確認
1	申請人受聘簽（申請人與科/部主任需簽章）		
2	臨床試驗計畫摘要（英文）及計畫書		
3	臨床試驗諮詢委員合約書 1 式 3 份 ● 申請人與聘任機構須先簽署 ● 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 ● TERMS ● SERVICES ● HONORARIA AND OUT-OF-POCKET COSTS ● ACCOUNT INFORMATION（入本院 401 專戶之 PI 臨床試驗帳戶）		

聯絡人：	**機構：**	**職稱：**
日期：	Tel:	Email:

醫研部收件人簽章/日期： _____ ☐文件不足，請補件 ☐送件資料無誤

附件二、經費表

臨床試驗經費總預算（Clinical Trial Budget Summary）

一、 研究倫理委員會案件編號 (IRB No.)：

二、 計畫名稱 (Protocol Title)：

三、 計畫主持人 (Principal Investigator)：

四、 贊助者 (Sponsor)/受託研究機構(CRO)：

五、 計畫執行期間 (Duration of Study) ：○○○○年○○月○○日至○○○○年○○月○○日，若有變更以研究倫理委員會最新核准期間為準

六、 預估收案人數 (Target Enrolment) ：_____人

七、 臨床試驗經費總表 (Clinical Trial Budget Summary)（單位：新台幣元）(currency: NTD)

	Item	Cost per patient (NT$)	Estimated Total Cost (NT$) for ____ patients	Remark
1	主持人費/協同主持人費 Principle Investigator/ Sub-Investigator Fee			1. 經費存入 OOOO。 2. 本經費可供出國參加學術會議之註冊費、交通費及生活費等（依國外出差旅費報支要點）。 【以下填寫說明，送件前請刪除】 帳戶設立方式請詳業務 Q&A，網址：https://www.ntuh.gov.tw/NCTRC/Faq.action?q_type=A01&fid=1118&agroup=a#1118。
2	研究護理師費/研究助理費 Study Coordinator/ Study Assistant Fee			1. 明細另列於 Table 1/月薪 OOO 元 2. 經費存入 OOOO 【以下填寫說明，送件前請刪除】 (1) 若以月薪編列請列算式，包含月薪、雇主負擔之保費(勞保、健保、勞退)、年終。 (2) 若以兼職費用編列須依現行費率外加全民健保補充保費。
3	檢查費/檢驗費 Examination/ Laboratory Fee			1. 明細另列於 Table 1 2. 使用記帳扣款系統 【以下填寫說明，送件前請刪除】 (1) 若非必要請勿列算式 (2) 依據臺北市政府衛生局(北市衛醫字第1083125664 號函)及本院醫療事務室(校附醫醫事字第 1091700288 號函)公告，無健保卡之外國籍人士自費就醫費用自 109 年 4 月 1 日起由健保價的 1.3 倍調增為 1.69 倍。臨床試驗外籍受試者比照上述費用規則，編列預算時敬請注意。

	Item	Cost per patient (NT$)	Estimated Total Cost (NT$) for ____ patients	Remark
4	門診費/住院費 Outpatient Fee/ Hospitalization Fee			1. 明細另列於 Table 1 2. 使用記帳扣款系統 【以下填寫說明，送件前請刪除】 (1) 若非必要請勿列算式 (2) 門診費包含"掛號費"及"診察費"。
5	受試者補償費 Participant Reimbursement/ Compensation Fee			(1) 明細另列於 Table 1 (2) 本經費包含公提全民健保補充保費 (3) 經費存入 OOOO 此項未編列可刪除 【以下填寫說明，送件前請刪除】 (1) 若非必要請勿列算式 (2) 本項目為提供受試者之車馬費、營養費等補償費用，所有費用皆應編列雇主負擔之全民健保補充保費，建議以 by visit 計算，勿以加總直接乘現行費率
6	證書申請費 Lab Certification Fee			此項未編列可刪除 【以下填寫說明，送件前請刪除】 經費編列參考 (1) 檢驗醫學部： www.ntuh.gov.tw/labmed/Download.action?q_type=A02&agroup=a (2) 病理部： https://www.ntuh.gov.tw/path/Fpage.action?muid=8&fid=7328
7	其他臨床試驗相關費用 Miscellaneous Fee			1. 用途/項目/金額 OOOOO 2. 經費存入 OOOO 此項未編列可刪除 【以下填寫說明，送件前請刪除】 經費使用請循本院採購相關規定辦理
8	其他費用 若有不足請自行在倉儲費之上增加欄位			1. 用途/項目/金額 OOOOO 2. 經費存入 OOOO 此項未編列可刪除
9	文件倉儲費 Study Data Storage Fee			1. 金額說明 2. 經費存入 OOOO 【以下填寫說明，送件前請刪除】

	Item	Cost per patient (NT$)	Estimated Total Cost (NT$) for ____ patients	Remark
				本項不可刪除，如未編列請說明原因
10	藥品管理費 Investigational Drug Management Fee			1. 第一年費用 OOO 2. 第 2 年之後費用 000 元/年，共編列 OO 年。 【以下填寫說明，送件前請刪除】 (1) 本項不可刪除，若未編列須說明原因，藥品臨床試驗若未編列需檢附免除藥品管理費奉核簽陳 (2) 請列提供經藥師核章確認之藥品管理費評估表 (3) 參考資訊 - 臨床試驗用藥管理中心：https://www.ntuh.gov.tw/NCTRC/Fpage.action?muid=2940&fid=2766
11	管理費/統籌發展費 (17%) Overhead (17%)			Items 1-10 之總和 x 17%
12	總經費 Total			Items 1-11 之總和

備註：

1. 入臺大醫院經費皆另收取管理費，因試驗傷害由廠商直接賠償受試者且未入臺大醫院之費用則不收取管理費。
   The budget for National Taiwan University Hospital (NTUH) shall be charged with a separate administration fee (overhead). Due to study injury, any costs paid directly by the sponsor to the subject, which are not budgeted for NTUH shall be exempted from overhead charges.
2. 受試者回診相關費用（如檢查費/檢驗費、門診費/住院費、受試者車馬費/營養費等）需足額繳納，不可預扣；若前述費用在試驗執行中有不足之情況，應盡速補足經費，不受定期支付之限制。
   Expenses related to subjects' follow-up visits (such as examination/lab fees, outpatient fees /hospitalization fees, subject transportation/nutrition reimbursement fees) must be paid in full and cannot be withheld in advance. If there is any shortfall in the aforementioned expenses during the trial, the funds should be promptly supplemented without being subject to the limitations of regular payments.
3. 若收案超過經費表預估總人數，主持人費、研究護理師/研究助理費、檢查/檢驗費、掛號/住院費、受試者車馬費/營養費等，將以經費總表所列之金額，依實際收案人數與發生診次支付，其他臨床試驗相關費用（起始費/雜支等），將以實際發生次數（或年度）支付，藥品管理費則依「藥品管理費評估表」計費。
   If the number of enrolled cases exceeds the estimated total number of subjects in the budget table, the Principal Investigator/Sub-Investigator fee, Study Coordinator/Research Assistant Fee, examination/lab fees, OPD registration/hospitalization fees, subject transportation/nutrition reimbursement fees, etc., will be paid based on the amounts listed in the budget table, according to the actual number of enrolled subjects and the number of visits incurred. Other related expenses for the clinical trial (initial fees/miscellaneous expenses, etc.) will be paid based on the actual number of

occurrences (or annually). The drug management fee will be charged according to the "Investigational Management Fee Assessment Form."

八、 實支實付項目 (Invoiceable/Conditional Payment)

九、 付款時間表及經費繳納方式 (Payment Terms & Methods)

1. 付款時間表：

(1) 預付款：合約簽署完成後○日內支付○○○元，包含以下項目（請自行填寫）

【藥品臨床試驗預付款說明】正式送件請刪除本段

- 需至少預付 30% 收案病人完整執行治療之醫療費用（包含檢查費、檢驗費、門診費、住院費等需存記帳扣款系統之費用）及受試者補償費用（如車馬費、營養費等）。
- 若有編列高單價之實支實付檢查項目，例如 PET、MRI、CT 等影像學類檢查或高單價額外用藥等，需預付至少 30%收案病人可能所需之費用，例如 30%收案病人各一次，避免記帳扣款系統欠款導致執行問題。
- 以上費用於計畫結案後，結算若有**溢繳**可退還。

(2) 後續付款：（請自行填寫）

2. 經費繳納方式：

(1) 經費繳納方式（匯款、支票、臨櫃繳納等請自行填寫）

(2) 付款資訊 (payment information)

戶名(Beneficiary's name): 台大醫院作業基金 401 專戶
(National Taiwan University Hospital)

銀行(Beneficiary's bank): 合作金庫商業銀行台大分行
(TAIWAN COOPERATIVE BANK, TAI-DA BRANCH)

帳號(Account no.): 1346 713 100 100

SWIFT CODE: TACBTWTP

Table 1. 臨床試驗經費支付明細表（Patient Visit Schedule and payment in NT$ per patient and total patients）

項目 Item	Screening	Treatment															Cost per patient	Total Cost for ___ patients
Visit Schedule																		
Day (week or month)																		
主持人費/協同主持人費 Principle Investigator/Sub-Investigator Fee																		
研究護理師/研究助理費 Study Coordinator/Study Assistant Fee																		
檢查費/ 檢驗費 Examination/ Laboratory Fee	檢查檢驗費小計																	
門診費 Outpatient Fee																		
住院費 Hospitalization Fee																		
受試者車馬費/營養費 Subject Traveling/Nutrition Reimburse Fee																		

填寫說明：

1. Patient Visit Schedule：須標示時間單位（day or week or month）。
2. 檢查檢驗費：須列出各項檢查檢驗明細項目。例：ECG、CXR、CT Scan 等。
3. 若非必要，非 by visit 支付的經費（例如雜項支出、證書申請費、倉儲費、藥品管理費、小計、總計等等）請勿列在支付明細表。

附件三、合約紙本用印流程

一、請委託/贊助方或合作機構，及計畫主持人先完成合約簽署。

二、簽陳製作請至公文系統以「紙本創文」，並設定會辦 (1)醫學研究部、(2)主計室，列印紙本後請計畫主持人與科部主任核章，並請將系統上簽陳流程送出；研究者自行發起計畫若贊助者未贊助經費，不需會辦主計室。

三、所有文件依據檢核表按順序排列，並且製作 A4 隔頁式側標，側標樣式可參考文件下載 1-5，側標勿重疊、勿將標籤直接黏貼於文件或透明資料袋。

四、整份文件以院內公文傳遞方式送至醫學研究部臨床試驗中心；如採郵寄或快遞，收件時間為每週一至週五（國定假日除外）8:00-12:00、13:00-17:00，地址為 100025 臺北市中正區徐州路 17 號 8 樓臨床試驗中心

五、用印時效：

（一）本中心收到紙本文件並確認內容無誤後，會 email 發送「收到紙本文件通知」，**約 7 工作日**後可完成用印。

（二）完成用印後，會 email 發送「合約發文通知」，由於公文傳遞流程，**約 4 至 5 個工作日**後廠商會收到郵局掛號寄送之合約正本。