**【亞東紀念醫院廠商贊助臨床試驗研究計畫合約簽署】審核文件確認表**

| 計畫主持人 | |  | 執行單位 | |  | |
| --- | --- | --- | --- | --- | --- | --- |
| 贊助者(廠商) | |  | 廠商聯絡人 | |  | |
| 聯絡電話 | |  | E-mail | |  | |
| 計畫編號 | | (IRB案號六碼 - 英文字母) | | | | |
| 計畫名稱 | |  | | | | |
| 文件名稱-依順序排列 | | | | 贊助商  (**已有請打勾**) | | 臨床試驗中心  (**確認**) |
| **1** | **廠商發函之正式公文**  **(受文者請署名 ”亞東紀念醫院 臨床試驗中心 ”)** | | |  | |  |
| **2** | **合約書/協議書一式三份** | | | □本院制式合約  □廠商自訂合約 | |  |
| **3** | **用藥管理合約附簽一式三份**  （1）藥品管理費免收10%管理費  （2）試驗委託者應於簽約前主動向藥學部（分機2336）確認藥品管理費之金額 | | |  | |  |
| **4** | **有贊助者之臨床試驗計畫合約書附簽一式三份**  若因計畫需要非正職人員進出本院門禁管制區(如：各實驗室)須繳交10,000元之行政管理費用 | | |  | |  |
| **5** | **亞東紀念醫院有贊助者之臨床試驗申請書** | | |  | |  |
| **6** | **亞東紀念醫院人體試驗審議委員會同意函** | | |  | |  |
| **7** | **衛生福利部人體試驗同意函** | | |  | |  |
| **8** | **檢驗相關證書影本**  包含：TAF證書、檢驗項目參考值、實驗室負責人CV  一份5,000元 (不含10%管理費)  若有相關疑問請洽：臨床病理科總醫檢師何鎔莉(1119) | | | □需申請  □不需申請 | |  |
| **9** | **申請記帳代碼**：提供主持人做為登記計畫內需支付的檢查或檢驗等相關費用，以便醫療事務處建立醫療費用之扣帳系統。 | | | □需申請  □不需申請 | |  |
| **10** | **電子檔1份**：內含上述所附申請文件。E-mail至臨床試驗中心。（E-mail：[**femh96982@mail.femh.org.tw**](mailto:femh96982@mail.femh.org.tw)） | | |  | |  |

**臨床試驗合約書/協議書條文檢核表(新案)**

本院簽訂之臨床試驗計畫合約書應填妥此表送審，以下項目已AAHRPP為依據基準，若有不明確之處，將請試驗委託者依以下內容進行合約條文調整。

This checklist should be submitted with the Clinical Trial Agreement signed by FEMH; the following items are in conformance with AAHRPP Standards.

| 1. 受試者若因參加臨床試驗而造成死亡、傷害、不良反應或其他損害，應由試驗機構及試驗主持人提供專業醫療照護及諮詢，試驗委託者應支付所需之合理醫療費用及損害賠償。(參照AAHRPP評鑑基準第1.8.A條規定)   If death, injury, adverse reaction or other damage to a study subject is directly related to participation in the study, the Institution and the PI shall provide professional care or consultation, and the Sponsor shall pay for reasonable medical expenses or compensation for damage.  ⬜ 是，已有約定於合約書中第ˍˍˍˍ頁第ˍˍˍˍ條  　 Yes, already agreed upon and cited on pageˍˍˍˍand lineˍˍˍˍin the contract.  ⬜ 否，請說明：ˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍ  　 No, please comment |
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| 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，應立即通報亞東醫院人體試驗審議委員會、計畫主持人及受試者保護中心。（參照AAHRPP評鑑基準第I.8.B.條規定）   In studies where Sponsors conduct research site monitoring visits or conduct monitoring activities remotely, the Sponsor should promptly report to the Far Eastern Memorial Hospital IRB, principal investigator and Human Research Protection Center any findings that could affect the safety of participants or influence the conduct of the study.  ⬜ 是，已有約定於合約書中第ˍˍˍˍ頁第ˍˍˍˍ條  　 Yes, already agreed upon and cited on pageˍˍˍˍand lineˍˍˍˍin the contract.  ⬜ 否，請說明：ˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍ  　 No, please comment \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 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亞東醫院人體試驗審議委員會。並說明提供例行報告及緊急報告之時程。（參照AAHRPP評鑑基準第I.8.C.條規定）   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.  ⬜ 是，已有約定於合約書中第ˍˍˍˍ頁第ˍˍˍˍ條  　 Yes, already agreed upon and cited on pageˍˍˍˍand lineˍˍˍˍin the contract.  ⬜ 否，請說明：ˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍ  　 No, please comment \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. 試驗委託者於臨床試驗結束後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亞東醫院人體試驗審議委員會，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。（參照AAHRPP評鑑基準第I.8.E.條規定）   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 Far Eastern Memorial Hospital (Research Ethics Review Committee) in order to consider informing participants. The steps and the time frame (two years after a research study has ended) followed to communicate findings should be specified.  ⬜ 是，已有約定於合約書中第ˍˍˍˍ頁第ˍˍˍˍ條  　 Yes, already agreed upon and cited on pageˍˍˍˍand lineˍˍˍˍin the contract.  ⬜ 否，請說明：ˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍ  　 No, please comment \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| ※本院覆核審查意見Evaluation by FEMH：ˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍˍ  日期Date : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |