廠商贊助研究計畫合約申請及審查表

(未依照本院範本)

院區別： IRB案號： 日期： 年 月 日

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 合約類別 | □廠商委託(□新案□變更案)  □主持人自行發起、廠商部分贊助(□新案□變更案) | | | | | | |
| 試驗名稱 |  | | | | | | |
| 主持人 |  | | | | | | |
| 委託廠商 |  | 聯絡人 |  | 電話 |  | e-mail |  |
| CRO |  | 聯絡人 |  | 電話 |  | e-mail |  |
| SMO |  | 聯絡人 |  | 電話 |  | e-mail |  |
| ※未依長庚醫院「臨床試驗合約書」範本內容簽訂合約  一、已依「廠商贊助研究計畫合約及計畫案號送審文件確認清單」檢附相關文件。  二、若為廠商全額贊助計畫，已了解臨床試驗合約書第九條「任何發明或發現(不論是否能取得專利)創新、建議、設想和報告或其他由試驗機構或計畫主持人做出或開發出與試驗相關的智慧財產，將成為試驗委託者專屬財產」。  三、增修訂條文內容說明如下表：中英文合約皆須檢附此表。   |  |  |  | | --- | --- | --- | | 原條文 | 增修訂條文內容 | 說明 | |  |  |  | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 三、請於合約內容項目表自我申報：   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | 合約內容項目 | 送件者 | | | 臨床試驗中心/醫研部審查 | | | | | 頁數 | 條文 | 送件確認 | 收件確認 | 符合 | 不  符合 | 備註 | | 1.本次為合約變更案，不須填寫。 |  |  |  |  |  |  |  | | 2.載明的試驗計畫名稱，與IRB核准函相同。 |  |  |  |  |  |  |  | | 3.載明的主持人姓名，與IRB核准函相同。 |  |  |  |  |  |  |  | | 4.研究護師或助理係由本院臨床試驗中心所提供。 |  |  |  |  |  |  |  | | 5.本案屬藥品臨床試驗：第\_\_\_\_\_期。 |  |  |  |  |  |  |  | | 6.本案屬觀察性、非介入性、病歷回溯或問卷調查等類型之試驗。 |  |  |  |  |  |  |  | | 7.本案試驗標的物屬「食品/特殊營養品/化妝品/可於公開通路販售之商品」。 |  |  |  |  |  |  |  | | 8.本試驗有蒐集檢體(或已於試驗計畫書中約定處理方式)。 |  |  |  |  |  |  |  | | 9.本試驗需經衛福部核准。 | --- | --- |  |  |  |  |  | | 10.本試驗有委任CRO執行。 | --- | --- |  |  |  |  |  | | 11.智慧財產權歸屬合理。 | --- | --- |  |  |  |  |  | | 12.行政管理約定(1)~(6)： |  |  |  |  |  |  |  | | (1)若有超付款項試驗委託者應配合甲方之規定辦理超付款項退還作業。計畫案終止剩餘款項試驗委託者應於IRB結案後一年內需完成申請退款作業，逾期試驗機構得不受理退費。 |  |  |  |  |  |  |  | | (2)試驗機構於本計畫執行期間，如因研究需要，須試驗委託者提供必要之人員(應由試驗委託者聘任或由試驗委託者委任CRO或SMO公司辦理)、所需研究耗材、藥品及其他相關事項之協助時，試驗委託者應盡力配合。 |  |  |  |  |  |  |  | | (3)試驗機構及試驗主持人同意試驗委託者、倫理委員會及主管機關透過事先安排，於營業時間內查核試驗相關資料及設施，試驗委託者應於一週前通知試驗機構及試驗主持人，告知預計查核之目的、來訪人員、查核個案與所需文件，且試驗委託者應配合試驗機構病歷閱覽規定辦理。 |  |  |  |  |  |  |  | | (4)已上市儀器設備試驗機構得接受試驗委託者捐贈或借用，由試驗機構給予材料編號並納入甲方固定資產管理；未上市儀器設備試驗機構不接受試驗委託者捐贈，以試驗機構之借用規定辦理，由試驗委託者負責醫材定期保養、維修作業和相關費用支出，並提供維修紀錄予試驗機構存查。 |  |  |  |  |  |  |  | | (5)任何試驗委託者所提供的器材和材料，包括未使用的試驗性藥物、未使用的個案報告表，如依法規及試驗計畫書規定或逾使用期限等情形致未能提供受試者使用時；試驗委託者應自試驗機構通之後六十日內予以回收，如有遲延，試驗機構得以「對方付費」之快遞方式寄予試驗委託者，且運送過程相關風險均由試驗委託者承擔。 |  |  |  |  |  |  |  | | (6)於合約中載明計畫執行費用。 |  |  |  |  |  |  |  | | (7)合約中損害賠償對象須與受試者同意書一致。 |  |  |  |  |  |  |  | | 臨床試驗中心/醫研部經辦人員： | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | 合約內容項目 | 送件者 | | | 醫療專家審查 | | | | | 頁數 | 條文 | 送件確認 | 收件確認 | 符合 | 不  符合 | 備註 | | 13.載明受試者保護條例(醫療專家審查)： |  | | | | | | | | (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，包含醫療提供者及支付費用者：如依本研究所訂臨床試驗計畫因而發生不良事件或造成受試者的損害，應由試驗機構提供專業醫療照護及諮詢，必要之醫療費用由(有贊助廠商：試驗委託者)(無贊助廠商：試驗機構及試驗主持人)負擔。(AAHRPP 1.8 A) |  |  |  |  |  |  |  | | (2)如試驗委託者執行臨床試驗之安全監測，發現對受試者有安全疑慮及影響臨床試驗之執行時，應立即通報本院IRB及主持人。(AAHRPP 1.8 B) |  |  |  |  |  |  |  | | (3)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，應依照試驗機構或IRB規範的時間內，提供安全監測報告予本院IRB及主持人。(AAHRPP 1.8 C) |  |  |  |  |  |  |  | | (4)在研究開始之前，關於研究結果之公布及研究者與贊助者在發表所扮演的角色，本院與贊助者需有書面的協議。(AAHRPP 1.8 D) |  |  |  |  |  |  |  | | (5)於臨床試驗結束後2年內，如發現非預期且直接影響受試者安全之疑慮，試驗委託者應以公函通知本院IRB及主持人，以利通知受試者。(AAHRPP 1.8 E)。 |  |  |  |  |  |  |  | | (6)如試驗委託者有授權其他臨床研究機構(CRO)執行本臨床試驗，試驗委託者應檢附授權CRO之授權書。關於維護試驗數據的品質與完整性之最終責任，仍應由試驗委託者負責。(JCIA HRP3.1) |  |  |  |  |  |  |  | | (7)試驗委託者確保研究數據之可靠性和有效性，及研究結果與報告是符合倫理，且統計準確無偏差。(JCIA HRP3) |  |  |  |  |  |  |  | | 醫療專家： | | | | | | | | | 合約內容項目 | 送件者 | | | 法務組審查 | | | | | 頁數 | 條文 | 送件確認 | 收件確認 | 符合 | 不  符合 | 備註 | | 14.載明學術發表的權限。 |  |  |  |  |  |  |  | | 15.載明計畫成果之權利歸屬。 |  |  |  |  |  |  |  | | 16.載明試驗相關損害賠償責任，除因試驗機構或主持人之故意或過失所致者外，概由試驗委託者負全部責任。 |  |  |  |  |  |  |  | | 17.已載明名稱使用之相關約定與賠償。 |  |  |  |  |  |  |  | | 18.試驗委託者之合約簽署人為公司負責人，或已檢附授權書(後續廠商補正後，由臨床試驗中心確認)。 |  |  |  |  |  |  |  | | 19.其他： |  |  |  |  |  |  |  | | 法務人員： | | | | | | | |   申請人簽名（計畫主持人）： |

|  |
| --- |
| 四、初審意見：  □1.臨床試驗中心/醫研部：  (1)合約內容審核(若臨床試驗合約書(三方合約-廠商委託)第九條智財權歸屬有疑義，應請產學合作中心協助評估)：  (2)試驗經費審核：  主管： 經辦人員：  □2.法務室人員：  主管： 經辦人員：  □3.會簽單位\_\_\_\_\_\_\_ (若屬研究護師由本院臨床試驗中心所提供，應由該院區臨床試驗中心確認)  □產學合作中心人員(牽涉智財權比例分配者)  主管： 經辦人員： |
| 五、申請人審查意見回覆：(請依審查意見逐條說明回覆，如未依意見修改請敘明原因)  申請人簽名（計畫主持人）： |
| 六、複審意見：  □1.院區臨床試驗中心/醫研部：  主管： 經辦人員：  □2.法務室人員：  主管： 經辦人員：  □3.會簽單位\_\_\_\_\_\_\_  □產學合作中心人員(牽涉智財權比例分配者)  主管： 經辦人員： |
| 七、院區管理部 審核意見：  主管： 經辦人員：  院長： |

(書寫空間若不足請以附件方式呈現)