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| --- | --- | --- |
|  | **臺中榮民總醫院**  **Taichung Veterans General Hospital** |  |
|  | **臨床試驗計畫預算支用表**  **Clinical Trial Budget** |  |

**一、計畫基本資料 Basic Information of the Study:**

1. 計畫名稱：

Protocol Title:

1. IRB編號：

IRB Number:

1. 計畫主持人科別/姓名：

Division/Name of Principal Investigator:

1. 計畫執行日期：自合約簽署日起至 年 月 日

屆時若不如預期結果，可依雙方同意而延長。

Period of Clinical Trial Agreement Implementation: From Clinical Trial Agreement signing date to\_\_\_\_\_ year(s) \_\_\_\_\_ month(s) \_\_\_\_\_ day(s)

If the study has not yielded expected results by the end of the time period, the Study Implementation Time Period may be extended if both Parties (Sponsor and Institution) agree.

1. 計畫經費合計新台幣： 元整(含預算表合計\_\_元和合約審查費(於合約審查前已繳交) 元)。

經費支付應實際需要有更動時，得由雙方協議辦理經費變更增減預算。

Total Budget (NTD):\_\_\_\_\_\_\_\_\_\_NTD (including the total study budget \_\_\_\_\_\_\_ NTD and the attorney review fee (The payment shall be made before the review of the Clinical Trial Agreement) \_\_\_\_\_\_\_\_ NTD).

Changes, addition or deduction of the total budget can be made based on actual budget needs if both Parties agree after discussion.

1. 計畫經費之撥付方式：

Payment Schedule:

* + - 1. 合約簽署完成後需支付第一期款，共計新台幣 元，含計畫作業費 元(含主持人費 元、臨時工資資 元、醫療費用 元、受試者費用 元、其他 元)行政管理費 元、藥品管理費 元後始能執行計畫。

An initial payment of $ \_\_\_\_\_\_\_\_\_\_\_ NTD, representing the operating budget in the amount of $ \_\_\_\_\_\_\_\_\_\_ NTD, administrative management fee in the amount of $ \_\_\_\_\_\_\_\_ NTD, and d Investigational Product Management Fee $ \_\_\_\_\_\_ NTD.

* + - 1. 於合約審查前繳交律師審查費 元。

The payment for the legal review fee in the amount of $ \_\_\_\_\_\_ NTD shall be made before the review of the Clinical Trial Agreement.

* + - 1. 除上述1.之外，其餘款項支付時程，將以每 為單位進行支付， (請詳述支付)。

Subsequent payments shall be made on a regular basis except above point 1 mentioned. (please provide details of the monthly, quarterly, or other payment schedule).

* + - 1. 臨床試驗執行中，廠商應依據合約付款時程給付，若試驗機構已出具繳款明細及相關單據請款而未獲付款時，應依年息百分之五計算遲延利息，且得於45日期限之付款通知屆期後試驗機構有權中止計畫或終止合約。

In the course of the Study, the Sponsor shall pay to institution according to the contract payment schedule. detailed above. If the Institution has provided details and receipts of relevant expenses and payment from the Sponsor for reimbursement is not made, a 5% annual interest will be added to the delayed payment; the Sponsor shall make the payment in the full amount within 45 days after receiving a payment notice, otherwise the Institution may suspend or terminate the Study or the Agreement.

* + - 1. 各次計畫作業費繳款，將依據實際繳款金額另計10％為行政管理費。

An administrative management fee of 10% shall be added to each payment of the operating budget.

* + - 1. 若有經費不足時，應立即支付。

A payment shall be made promptly when expenses for the Study need to be covered immediately.

1. 合約洽談機構資料：(務必填寫)

Information of Contact Person of Collaborating Organizations: (Must be filled in)

1. 機構名稱Name of Organization：
2. 統一編號Tax ID Number:
3. 機構地址Address:
4. 聯絡人Contact Person:
5. 聯絡方式Contact Information:

* E-mail:
* Office:　　　　　　　　 手機Mobile：　　　　　傳真Fax：

1. 經費付款機構資料( □同上，以下省略。)：

Information of the Sponsor (□Same as above):

1. 機構名稱Name of Organization:
2. 統一編號Tax ID Number:
3. 機構地址Address:
4. 聯絡人Contact Person:
5. 聯絡方式Contact Information:

* E-mail:
* Office:　　　　　　　　 手機Mobile：　　　　　傳真Fax：

※上述聯絡人若是有更換，請主動e-mail: [**tcvghcrc@vghtc.gov.tw**](mailto:tcvghcrc@vghtc.gov.tw)通知臨床試驗中心，或計畫主持人請於得知人員更換訊息起**兩星期內**，同樣e-mail通知，以利更新聯絡資訊。

If there is any change to the aforesaid contact person, please take the initiative to email: tcvghcrc@vghtc.gov.tw to inform the Clinical Research Center; or the Principal Investigator should notify through the same e-mail **within two weeks** of being informed about the change of personnel, in order to update the contact information **二、預算表 Budget**

金額單位：新台幣元

Currency: New Taiwan Dollar (NTD)

|  |  |  |  |
| --- | --- | --- | --- |
| 項　　　　　　目  Item | | 金　　額  Amount | 說　　　　明  Notes |
| 計　畫  作業費  Operating Fee | ㄧ、用人費用  Manpoer Costs： |  |  |
| 主持人費  Principal Investigator Fees |  | (依據受試者實際完成的訪視支付，請參照經費表)   1. 每完成一位受試者約\_\_\_元x收\_\_位=小計\_\_\_元 2. 篩選失敗依據實際發生人數支付)每位受試者約\_\_\_元x預估\_\_位=小計\_\_\_元( 3. 非預期訪視(依據實際發生次數支付)每次約\_\_\_元x預估\_\_\_次=小計\_\_\_元 4. 實支實付：   (需外加雇主健保補充保費) |
| 專（兼）任助理薪資  Full-time (Part-time) Assistant Salary |  | 每月薪資約\_\_\_元x\_\_月=\_\_\_元+年終\_\_\_元=小計\_\_\_元  (需外加1.雇主勞健保費用2.年終獎金3.勞工退休金) |
| 臨時工工資  Temporary Workers Wages |  | (依據受試者實際完成的訪視支付，請參照經費表)   1. 每完成一位受試者約\_\_\_元x收\_\_位=小計\_\_\_元 2. 篩選失敗依據實際發生人數支付)每位受試者約\_\_\_元x預估\_\_位=小計\_\_\_元( 3. 非預期訪視(依據實際發生次數支付)每次約\_\_\_元x預估\_\_\_次=小計\_\_\_元 4. 實支實付：   (需外加1.雇主勞健保費用2.勞工退休金) |
| 二、服務費用  Service Costs: |  |  |
| 醫療費用  Medical Expenses |  | 試驗所需之門診/急診/住院之相關醫療費（如：掛號費、檢驗費、檢查費、住院費…等等）  如：   1. 掛號費：每次約\_\_\_元x每位\_\_\_次x收\_\_位=小計\_\_\_元 2. 篩選失敗： 3. 掛號費(依據實際發生人數支付)：每次約\_\_\_元x每位\_\_\_次x收\_\_位=小計\_\_\_元 4. 非預期訪視 5. 掛號費(依據實際發生次數支付)：每次約\_\_\_元x每位\_\_\_次x收\_\_位=小計\_\_\_元 6. 實支實付如： 7. 病床費：每次約\_\_\_元x每位\_\_\_次x收\_\_位=小計\_\_\_元 |
| 受試者費用  Subjects’Fees |  | 受試者之車馬費、營養費..等等。(依據受試者實際完成的訪視支付，請參照經費表)  如：   1. 車馬費：每次約\_\_\_元x每位\_\_\_次x收\_\_位=小計\_\_\_元 2. 篩選失敗： 3. 車馬費(依據實際發生人數支付)：每次約\_\_\_元x每位\_\_\_次x收\_\_位=小計\_\_\_元 4. 非預期訪視 5. 車馬費(依據實際發生次數支付)：每次約\_\_\_元x每位\_\_\_次x收\_\_位=小計\_\_\_元 |
| 旅運費  Travel and freight Fees |  |  |
| 三、材料及用品費  Materials and Supplies Cost: |  |  |
| 材料費  Materials Fees |  |  |
| 用品費  Supplies Fees |  |  |
| 四、其他：  Others Cost |  |  |
| 五、設備費(單價一萬元以上設備)： Equipment Cost (equipment of more than 10,000NT per item): |  |  |
| 管理費  Administrative Budget | 行政管理費  Overhead Fees |  | 為計畫作業費合計金額\*10%，此費用不退還。  Operating Fee\*10%, non-refundable |
| 藥品管理費  Investigational Product Management Fee |  | 第一年藥品管理\_\_\_元，以\_\_\_年計算，共計 元  First year Investigational Product Management Fee NT ;The estimate is calculated in years, totaling NT .。  第二年起每年將重新進行藥品管理費評估，並依據實際評估金額繳交。  From the second year onwards, the drug management fee will be evaluated again every year and paid based on the actual evaluation amount.  ※此費用不退還non-refundable。 |
| 合　　　　　計  Total | |  | 計畫作業費各項目金額除醫療費及受試者費用外，可由計畫主持人可自行決定流用，IRB計畫結案後則不再此限：■是 □否  The amount of each item of Operating Fee, except for Medical Expenses and Subjects’ Fees, can be decided and used by Principal Investigator. After the IRB project is closed, this limit is no longer limited: ■Yes □No |

**二、經費表(依訪視情形支付)**

| **項目** | **Screening** | **Treatment** | | | | | | | | | | | | | | | **Cost per patient** | **Total Cost**  **for patients** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Visit Schedule** |  |  | | |  | | |  | | |  | | |  | | | - | - |
| **一、用人費：** |  | | | | | | | | | | | | | | | |  |  |
| **主持人費** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **專（兼）任助理薪資** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **臨時工工資** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **二、服務費用：** |  | | | | | | | | | | | | | | | |  |  |
| **醫療費用** | 小計 | | | | | | | | | | | | | | | |  |  |
| 掛號費 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| EKG |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| X-ray |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 住院費 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **受試者費用** | 小計 | | | | | | | | | | | | | | | |  |  |
| 交通費 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 營養費 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **三、材料及用品費：** |  | | | | | | | | | | | | | | | |  |  |
| **四、其他：** |  | | | | | | | | | | | | | | | |  |  |
| **五、設備費：** |  | | | | | | | | | | | | | | | |  |  |
| **計畫作業費小計** |  | | | | | | | | | | | | | | | |  |  |
| **行政管理費(10%)** |  | | | | | | | | | | | | | | | |  |  |
| **藥品管理費** |  | | | | | | | | | | | | | | | |  |  |
| **總計：** |  | | | | | | | | | | | | | | | |  |  |

※以上預算編列請依照「臨床試驗計畫經費預算編列標準」。

　The above budget shall comply with the “Clinical Trial Budget Guidelines.”

※受試者相關費用須隨著研究進度支付，不可於研究完成之後再給付。

　The reward provided to the must be paid by stage during the research rather than paid after the research completion.

※如受試者主動或被動退出研究案，仍應按比例給予報酬或實支實付。

　If the participants actively or passively withdraws from the research, he/she should still be rewarded on a pro rata basis or be refunded for actual expenses.

※試驗委託者不得提供任何形式之轉介費（金錢或實物），或作為加速受試者的招募的酬勞。

　Sponsor does not allow to provide the referral fee in any forms (money or physical assets) as the reward for accelerating the recruitment of the subject.

上述經費業經雙方同意且確認無誤：

|  |  |
| --- | --- |
| 試驗委託者/受託研究機構：  (公司章或有權人簽章) | 試驗主持人：  (簽章) |
|  |  |

**臺中榮民總醫院**

**臨床試驗計畫經費預算編列標準**

**一、用人費用：**

（一）**主持人費：**試驗計畫執行期間，計畫主持人/協同主持人之試驗主持費，其支付依試驗合約預算編列執行，應包含雇主二代健保補充保費，依勞工局公告之負擔標準編列。

（二）**專/兼任助理薪資：**支應試驗計畫執行期間所需助理人員之每月薪資，其薪資比照院方規定，應包含若試驗計畫執行期間約用助理人員所需之勞保、健保保險費、勞工退休金，依勞工局公告之標準編列。

（三）**臨時工工資：**試驗計畫執行期間所需臨時僱用之工作人員，依試驗個案數計酬或按時支付臨時工資，應包含若試驗計畫執行期間約用助理人員所需之勞保、健保保險費、勞工退休金，依勞工局公告之標準編列。

**二、服務費用：**

（一）**醫療費用：**執行本計畫受試者所需之醫療費用：如掛號費、診察費、檢驗(查)費、病房費、住院膳食費．．．等費用，按本院收費標準編列。

（二）**受試者費用：**執行本計畫受試者所需之營養費、車馬費、禮品費、保險費等費用，依需要編列。

（三）**旅運費：**該計畫臨床試驗團隊研究人員為應試驗計畫所需之國內差旅費、國外差旅費、大陸地區旅費等，其中國外差旅費，須依「行政院及所屬各級機關因公派員出國案件編審要點」規定辦理。

**三、材料及用品費：**

（一）**材料費：**為應試驗計畫所需之衛材、藥品等相關費用。

（二）**用品費：**為應試驗計畫所需之實驗用品、辦公(事務)用品、郵電費、印刷及裝訂費等相關費用。

**四、其他：**為應試驗計畫所需之倉儲費、資料檢索、問卷調查、統計分析等與試驗計畫相關之各項費用；或辦理本試驗計畫所需不屬於以上之其他費用及雜支等。

**五、設備費：**凡執行本試驗計畫所需單價新臺幣一萬元以上且使用年限在二年以上之各項儀器、設備屬之；計畫結束後，其財產權歸屬依據合約規範辦理。

**六、管理費：**

（一）**行政管理費：**為各次計畫作業費實際繳款金額另計10%，為不退還之款項。

（二）**藥品管理費：**依本院臨床試驗藥局評估之收費標準編列，為不退還之款項。