**臨床試驗合約書條文檢核表(新案)**

**Clinical Trial Agreement Review Checklist**

本院簽訂之臨床試驗計畫合約書應填妥此表送審，以下項目以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 TCVGH; 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I.8.A.條規定）**If death, injury, adverse reaction or other damage to a Study Subject is related to participation in the Study, the Institution and the PI shall provide professional care and consultation, and the Sponsor shall pay for reasonable medical expenses and compensation for damage. (AAHRPP Element 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:：： \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**※本院覆核審查意見Evaluation by TCVGH：\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

* 1. **試驗委託者或其代理人應提供資料及安全監測報告給計畫主持人及人體研究倫理審查委員會；若發現受試者安全有疑慮或有影響臨床試驗執行之狀況，緊急事件應於10個工作天內、例行報告(如:安全監測報告)應於30個工作日內通報本院人體研究倫理審查委員會及受試者保護中心。**（參照AAHRPP評鑑基準第I.8.B.條規定）The Sponsor or its agents shall provide the principal investigator and the IRB with data and safety monitoring reports; if a concern about the safety of the subjects arises or if an event that affects the conduct of the Study occurs, the concern or the event shall be reported to the IRB and the HRPC (Human Research Protection Center) of TCVGH within 10 days in case of an emergency or within 30 days in case of a regular report (e.g. safety monitoring report).(AAHRPP Element I.8.B)

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 Yes, Already agreed upon and cited on page \_\_\_\_ and line \_\_\_\_in the contract; or other contract documents:\_\_\_\_\_\_\_\_\_\_\_\_

□否，請說明No, Please comment:：： \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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* 1. **臨床試驗期間，試驗委託者或其代理人若知悉試驗藥品發生非預期嚴重不良反應，應依法於期限內通報主管機關或其委託機構。(AAHRPP第I.8.C條；藥品優良試驗準則第106條)** During the course of the Study, if the Sponsor or its agents is aware of any event of unexpected serious adverse reaction, the Sponsor shall notify the competent authority or the contracted organization within the time limit in conformance with applicable laws and regulations.(AAHRPP Element I.8.C ; Article 106 of the Regulations for Good Clinical Practice)

□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:：： \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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1. **本試驗所產生之案例報告及其他資料(下稱資料)，悉歸試驗委託者所有，試驗委託者得以任何形式利用該資料。**
2. **本試驗所產生及包含於資料內之資訊，其智慧財產權歸試驗委託者所有，但涉及運用院方或計畫主持人技術成果或智慧財產所獲得者，另行協議之。**
3. **試驗委託者有權發表本試驗所產生之任何資料及資訊，毋須經試驗單位同意。**
4. **試驗單位對本試驗成果及由試驗委託者提供之背景資料，皆有發表權利，但應於發表前至少六十日送交試驗委託者；若試驗委託者於收到試驗單位提供之資料後有以下之情形，試驗單位便可自行發表：**
5. **若無任何無法抗拒之原因下，未於30日內提供回覆意見。**
6. **有專利/智慧財產權申請之考量，未於60日內提供回覆意見。**
7. **若該案發表對試驗委託者專利/智慧財產權有相關不利之影響，試驗委託者準備時間90日為限。**
8. **多中心之研究案：所有中心皆完成研究2年後，仍未發表研究成果。**
9. **研究案終止或結束10年以上**
10. **試驗委託者為可依下列條件之一者，有權要求修改發表內容：**
11. **發表內容之正確性。**
12. **智慧財產權已受到保護。c.已提供補充性資訊。**

 **(AAHRPP第I.8.D.條及第I.9條)**

1. Case reports or other data (hereinafter referred to as “Data”) produced from the Study shall belong to the Sponsor; the Sponsor may use the Data in any way or format.
2. The intellectual property rights of the Data from the Study shall belong to the Sponsor except for research results arising from using technology or intellectual property of TCVGH or the PI. The ownership of the intellectual property rights in the latter case shall be decided upon mutual agreement of both Parties.
3. The Sponsor has the right to publish any data or information arising from the Study without permission from the Institution conducting the Study.
4. The Institution has the right to publish results from the Study or background information provided by the Sponsor, but the Institution shall submit the manuscript to the Sponsor at least 60 days before the publication. If one of the following situations applies after the Sponsor receives the manuscript from the Institution, the Institution may publish the manuscript:
5. The Sponsor does not give any response or comments within 30 days without any occurrence of force majeure events.
6. There is concern regarding application for patent/intellectual property rights, and the Sponsor does not give any response or comments within 60 days.
7. If the publication of the manuscript has a negative impact on the patent or intellectual property rights of the Sponsor, the Sponsor will be allowed 90 days to respond and give comments to the Institution before the manuscript may be submitted for publication.
8. The Study is a multicenter study, and no research findings from the Study have been published at least two years after the Study has been completed in all participating centers.
9. The Study was terminated or closed more than ten years ago.
10. The Sponsor may request changes to the manuscript for publication if one of the following situations applies:
11. There is concern about the accuracy of the manuscript.
12. The intellectual property rights have been protected.
13. Supplementary information has been provided.

 (AAHRPP Element I.8.D & Element I.9)

□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:：： \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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* 1. **試驗委託者或其代理人於臨床試驗結束後(至少二年內)，若發現有非預期且直接影響受試者安全之資訊或重大事件，應自知悉日起十五日內，以書面通知計畫主持人、人體研究倫理審查委員會及受試者保護中心，由試驗單位評估是否通知受試者。(AAHRPP第I.8.E.條及第I.9條)**

Within two years after the closure of the Study, the Sponsor or its agents shall report in writing to the principal investigator, the IRB, and the HRPC upon discovery within 15 days of information or a serious event that may unexpectedly and directly affect the safety of the subjects ; the Institution conducting the Study shall evaluate whether subjects shall be notified of the information or event.(AAHRPP Element I.8.E & Element I.9 )

□是，已有約定於合約書中第\_\_\_頁第\_\_\_條，或其他合約文件：\_\_\_\_\_\_\_\_\_\_\_\_

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**F. 載明試驗須經衛生主管機關核准，始得執行。(AAHRPP第I.7.A.條及第I.7.B)**

F.It is specified in the Agreement that the Study must be approved by the Competent Health Authority before the implementation of the Study.(AAHRPP Element I.7.A & I.7.B)

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□否，請說明No, Please comment:：： \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**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。**