Contract Review Checklist
臨床試驗合約檢核表

HRPC 修訂日期：108/04/01

Applicant Information (申請人資料)

Sponsor(委託人)			
Protocol title(計畫名稱)			
Types of clinical trial (試驗類別)	☐Phase I ☐ Phase II ☐Phase III ☐Phase IV ☐BA/BE/PK ☐PMS ☐clinical research		
IRB application number(申請號)		IRB approval number(核可號)	
Prepare by(本表填寫人)	Name：_____Title：____Tel：_____ Email：		

Check list (委託人請自行檢核後，連同合約書送交合約審查單位審查)

(Please send us a copy of your contract along with the check list for reviewing.)

	Contents/Review Focus 內容/審查重點	Sponsor 委託人			Contract Reviewer 合約審查人		
		Yes	No*	Article No. of contract/ Description*	Yes	No	Note
1	**Content of the clinical trial** 載明之試驗計畫名稱，需與 IRB 核可函之名稱相同。 *簽約時應以 IRB 核可之版本作為合約附件 *Please state the title of the Clinical Trial.* *The title should be the same as the title approved by IRB.* ** Please include the IRB approved protocol & IRB approval letter in the final contract booklet.*						
2	**Authorization and approval by the Institutional Review Board** 載明試驗需經 IRB(及)衛生主管機關核准，始得執行。試驗主持人需遵守相關的 GCP 等法令與規範。 *The trial should be authorized by IRB (and) MOHW for implementation.*						
3	**Clinical organization and investigators** 載明試驗執行機構與主持人，並載明試驗執行機構須遵守相關規範並擔負相關責任。 *Please state the name of the institution and the name of the principal investigator(s) in the contract. The institution should comply with relevant laws and norms.*						
4	**Study implementation period or effective duration of contract** 載明生效期間與計畫執行期限。 *Please state in the contract the implementation period and/or the effective duration of the contract.*						
5	**Study funds** 載明計畫經費以及執行後不得返還之經費項目。 *簽約時應以本院臨床試驗中心、計畫主持人及 Sponsor 簽署核可之預算表作為合約附件。 *Please state the budget and non-refundable items.* **The attached budget sheet should be approved and signed by CRC, P.I. and the sponsor.*						
6	**Payment method** 載明付款方式 *Please state the payment method in the contract.*						
7	**Provision of clinical trial products and information** 載明試驗用品提供義務及使用範圍。 *Please state the provision obligation and the usage of the clinical trial products.*						
8	**Assistance in understanding and facilitating the implementation of this contract**						

	載明試驗執行機構及試驗主持人需配合委託方進行業務了解及稽核。 *Please state in the contract the institution and P.I. shall cooperate with the sponsor in reviewing and understanding related operations.*						
9	**Confidential obligation** 載明雙方的保密義務、範圍及時限。 *Please state the confidential obligation and its effective period.*						
10	**Academic publications I.8.D.** 載明學術發表的權限，取得共識。 *Please specify restriction on academic publications. Contracts or other funding agreements require the sponsor to follow CMMC's policies and procedures regarding the publication of findings from sponsored research.*						
11	**Attributions regarding study data and results** 載明計畫成果之權利歸屬。 *Please specify the distribution of study results.*						
12	**Specimen samples collected during the clinical trial** 載明試驗所得之檢體樣本需依相關規範處理。 *Please comply with relevant laws in collecting or disposing the specimen samples.*						
13	**The safety of participants I.8.B.** 載明若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 IRB 及受試者保護中心(30 天內)。 T*he sponsor should promptly (no longer than within 30 days) report to the CMMC IRB and HRPC any findings that could affect the safety of subjects or influence the conduct of the study.*						
14	**Reporting obligations I.8.E.** 載明不良反應通報之時間、義務及後續處理措施。試驗結束後若有受試者安全疑慮之事件，委託人必須通知試驗單位處理。 *Please state the findings emerge after a research study has ended that are unanticipated and directly affect the safety of past participants, the Sponsor should communicate findings to the principal investigator and CMMC IRB in order to consider informing subjects.*						
15	**Use of the institution's or sponsor's name** 載明非依法令或試驗機構同意，廠商不得使用試驗機構名稱進行商業使用。 *The sponsor is not allowed to use, unless otherwise approved, the name of the institution for business purposes.*						
16	**Termination of this contract** 載明合約終止之處理。是否兼顧受試者權益。 *The termination process protects the rights of the study participants.*						
17	**Indemnification I.8.A.** 載明試驗相關之損害賠償責任，載明除因試驗機構或試驗主持人所致之損害，委託方需負起所有因試驗造成之損害賠償責任，並對受試者作醫療照護安排。 *The sponsor is responsible for indemnifying the costs of injury to the participants and the costs of damage or losses unless otherwise specified.* *The sponsor shall also be responsible for the costs of damage or losses of the institution, investigators, and other personnel conducting the study as a result of any related incidents.*						
18	**Insurance Obligation** 載明委託方具有投保試驗保險之責，是否符合 IRB 核可之 ICF 對於受試者保險之要求，以保障受試者權益。(除 IRB 通過可免之外) *The sponsor shall maintain a general commercial*						

	liability insurance that complied with the requirement of IRB approved ICF.						
19	**Transfer or assignment of rights and obligations** 載明合約轉讓之處理。 *Please state the contract transferring process.*						
20	**Partial Invalidity** 本合約部分條款之全部或一部依法被認為無效時，其他條款仍應繼續有效。 *Regardless of whether the part of the contract or specific sections is considered invalid according to law, the remaining part of this contract is still effective.*						
21	**Declaration and guarantees** 保證人員資格、藥物品質與相關資料、皆需符合相關規範，且未侵犯他人權益。(包含人、事、地、物) *Guarantees the personnel qualifications, drug quality and relevant information, must comply with the relevant standards, and did not violate the rights of others. (Including people, things, places, objects).*						
22	**Compliance with the law and regulations** 載明試驗執行皆需符合相關法令規範。 *The implementation of the study should comply with relevant laws and norms.*						
23	**Effectiveness of the appendices** 載明附件與合約具等同效力，附件若有新版從新版約定。 *The latest approved Appendices are considered part of the contract.*						
24	**Interpretation of this contract and mediation of disputes** 載明合約糾紛處理原則。 *Please state the principles for mediation of the disputes.*						
25	**Management Contact** 載明合約聯絡人資料。 *Please state in the contract the contact person's contact information.*						
26	**Contract distribution/number of copies** 應有足夠的正本合約由試驗主持人、執行試驗之醫院留存。其他依 Sponsor 需求增加。 *Prepare enough copies of contract for P.Is, and the institution. Additional copies made upon sponsor's request.*						
27	**Reports of data and safety monitor I.8.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 IRB。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 of data and safety monitor to the Principal Investigator who forwards them to CMMC IRB. The time frame for providing routine and urgent data and safety monitor reports should be specified.*						
28	**Other issues** 試驗委託者有授權臨床研究機構(CRO)執行本臨床試驗，且檢附授權 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，應由試驗委託者負責。 *Sponsors had authorized clinical research organization (CRO) to perform this clinical trial, The ultimate responsibility for the maintenance of trial data on the quality and integrity shall be responsible by Sponsor.*						

29	研究經費不可使用健保費用 *Do not use health care costs in research funding.*						

Contract Reviewer：
合約審查人

Date：
日期

備註：

A. 臨床試驗有造成受試者傷害之虞者，送件人(廠商)應敘明其醫療安排，包括提供醫療者及支付費用者。(參照 AAHRPP 評鑑基準第 I.8.A.條規定)
A. 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.

B. 如送件人(廠商) 自行執行臨床試驗之安全監測，於試驗執行中發現有安全疑慮時，應立即通報奇美醫院。(參照 AAHRPP 評鑑基準第 I.8.B.條規定)
B. In studies where Sponsors conduct research site monitoring visits or conduct monitoring activities remotely, the Sponsor should promptly reports to the Chi Mei Medical Center any findings that could affect the safety of participants or influence the conduct of the study.

C. 如送件人 (廠商) 負責臨床試驗之資料與安全監測，應定期提出監測報告給計畫主持人，轉送奇美醫院人體試驗委員會審查。必要時，並應提出緊急報告。(參照 AAHRPP 評鑑基準第 I.8.C.條規定)
C. 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 Primary Investigator who forwards them to the CMMC IRB. The time frame for providing routine and urgent data and safety monitoring reports should be specified.

D. 合約載明學術發表的權限，取得共識。(參照 AAHRPP 評鑑基準第 I.8.D.條規定)
D. Please specify restriction on academic publications on Agreement Article for Publication of Research Finding.

E. 於試驗結束後(原則上二年內)，如發現非預期且可能影響受試者安全之疑慮，應通知計畫主持人或奇美醫院，以利決定是否通知受試者。(參照 AAHRPP 評鑑基準第 I.8.E.條規定)
E. 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 Research or the Chi Mei Medical Center in order to consider informing participants. The steps and the time frame (usually two years) followed to communicate findings should be specified.

臨床試驗成果發表合約書條文參考範本

[Template Agreement Article for Publication of Research Finding]

「醫療機構」及「主持人」可自行發表其在執行「臨床試驗」調查所發現的結果。凡尤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「醫療機構」及「主持人」決定。唯「醫療機構」或「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」；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」。「試驗委託者」可就發表指出的結果及結論向「醫療機構」或「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」識別出其中可能含有「試驗委託者」的「機密訊息」（以下條款釋義）者，「醫療機構」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」人員提出感謝的聲明。在任何文稿經發表後，「試驗委託者」即可任意使用、複製及分派該文稿，並無須對「醫療機構」持有任何義務。

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