彰化基督教醫療財團法人彰化基督教醫院
臨床試驗院外研究專員監測稽核作業辦法
Changhua Christian Hospital
Operation Guidelines for Monitory/Auditing of Clinical Trials by External Research Associate

1. 由議約窗口於試驗案簽約完成，通知試驗案成本中心時，一併告知試驗委託者/受託研究機構，應於試驗案初次監測前,正式來文告知本院臨床試驗案所指派的監測/稽核人員身份，並請監測/稽核人員完成彰化基督教醫院院外監測/稽核人員之教育訓練與測驗。

1.The contract contact window shall inform the trial center that before the first official monitoring of the study trial, an official letter bearing the identity of the monitoring/auditing personnel appointed for this clinical trial should be issued by the trial sponsor and institution. The contact window should inform the auditing/monitoring personnel to complete the education training and testing for external research specialist prepared by the Changhua Christian Hospital.

1-1 臨床試驗案所指派的監測/稽核人員來院初次監測/稽核前，試驗委託者/受託研究機構應先來文告知其所指派的監測/稽核人員之身分。

1-1 Before the first official monitoring of the study trial, an official letter bearing the identity of the monitoring/auditing personnel appointed for this clinical trial should be issued by the trial sponsor and institution.

1-2 公文之受文者為本院臨床試驗中心,若非臨床試驗中心執行之試驗案，受文者為該試驗案主持人。公文內容應包含:試驗計畫書編號、監測/稽核人員中英文姓名、試驗委託者/受託研究機構名稱。

1-2 The recipient of the official letter should be the Clinical Trial Center. The content of the letter should include: study protocol number, Chinese/English names of the monitoring/auditing personnel, and names of the trial sponsor/trial institution.

1-3 若同一試驗案後續的監測/稽核人員皆與初次相同，則後續的監測/稽核可以 e-mail 通知即可。

1-3 If the monitoring/auditing personnel for the subsequent monitoring of a same trial are identical, any follow-up monitoring/auditing may be notified by emails.

1-4 試驗委託者/受託研究機構若更換監測/稽核人員，應於更換人員後，來院監測之前，再次來文告知本院，公文內容與 1-2 同。

1-4 If the monitoring/auditing personnel has been replaced by the trial sponsor/institution, please notify our hospital via letter before the monitoring takes place. The content of the letter is identical to 1-2.

1-5 試驗委託者/受託研究機構之公文紙本,由秘書室轉送到本院臨床試驗中心/試驗主持人後，由研究個案管理師上傳 CTC 系統，並留存於主持人研究機構手冊。

1-5 Letter texts from the trial sponsor/institution will be delivered by section chief to be kept by the clinicl research coordinator in the principal

investigator's research brochure, after they have been transferred from the secretariat office to the Clinical Trial Center.

1-6 被指派的監測/稽核人員自臨床試驗合約簽約後至到本院執行監測/稽核前，皆可至彰基臨床試驗中心網頁下載課程檔案，並依檔案指示至 google 網頁考試，系統將自動告知測驗結果，測驗不限次數，分數須達 70 分以上始為及格。有效期限自考試通過日到當年 12 月 31 日，每年 1 月 1 日須再重新考試取得認證。

1-6 The appointed monitoring/auditing personnel, after they have signed an contract agreement with the Clinical Trial Center and before their first monitoring/auditing duty, may proceed to the Clinical Trial Center's website and download the education course files, and partake in a Google web test via the instruction in the file. The system will automatically calculate and display the test results. Tests can be repeated as necessary, and a score of 70 or above is needed to pass the test. The valid period of the test starts from the day the test was passed to December 31 of the current year. A re-certification is needed starting from January 1 of each year.

2.研究個案管理師接獲監測或稽核通知,確認與試驗委託者/受託機構正式來文所告知監測/稽核人員身份是否一致，若為一致，則安排監測時間與借場地；若不一致，則請試驗委託者/受託機構補通知公文，待公文齊全，才可進行監測。

2. After receiving the notification for monitoring/auditing, the clinical reasearch coordinator will verify whether the identity of the monitor/auditor is identical with the list included in the notification letters from the trial sponsor/institution.

If the identity is consistent, the clinical reasearch coordinator will arrange the schedule and location for monitoring; if not, the trial sponsor/institution is required to re-submit a notification letter before any monitoring is to take place.

3. 被指派的監測/稽核人員到本院執行監測/稽核時，應簽具保密切結書及出示證件以供核對。可接受的證件有:國民身份證、護照、健保卡、駕照。

3. Appointed monitor/auditor should sign a non-disclosure agreement and have personal identifications ready for verification. Acceptable identification documents include PID card, pass port, NIH card or driver's license.

4.被指派的監測/稽核人員於本院監測/稽核期間，請隨身佩帶本院發給之臨時黃卡識別證(上有監測日期)。(本證由臨床試驗中心提供，上面會註明監測/稽核期間。由研究個案管理師於監測/稽核於當日列印臨時識別證交由監測/稽核人員佩帶，結束後交還研究個案管理師)

4. All appointed monitor/auditor must wear a temporary yellow identification badge (monitoring dates inscribed on the badge) at all time, which will be issued by the hospital during their monitoring/auditing duration. The badge will be provided by the Clinical Trial Center and will inscribe the duration of the monitoring/auditing periods. The badges will be given to the monitor/auditor on the date of the monitoring by the clinical research coordinator, and will be returned to the clinical research coordinator after the monitoring has concluded.

5.資訊發展組成員每週至 google 系統確認考試合格名單，製作證書並加蓋單位證明章，以 E-mail 寄送證書。

5. Members of the Division of Information Development will check the google system weekly for list of individuals who have passed the online test, and will produce certificates with seals of proof. The certificates will be sent via email.

6.研究個案管理師向事務員借場地時，須填寫借用診間申請表，確認臨床試驗專員已完成教育訓練，始可借用場地。若臨床試驗專員尚未完成教育訓練，請事務員通知研究個案管理師聯繫臨床研究專員於執行監測前完成線上訓練，由資訊發展組人員確認後，始得進入彰基 HIS 系統開始進行監測作業。

6. The clinical research coordinator must submit the education training proof of the monitor/auditor before they can lease the venue from the general clerks. If not, the clinical research associate must complete the online training before their scheduled monitoring, and can only access the Changhua Christian Hospital HIS system after verification by the staff from the Division of Information Development.