Changhua Christian Hospital
Operation Guidelines for Monitory/Auditing of Clinical Trials by External Research Associate

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 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 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 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   1-4 If the monitoring/auditing personnel has been replaced by the trial sponsor/institution, please notify our hospital via letter before the monitoring takes place.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 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 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 (http://www2.cch.org.tw/layout_5/page.aspx?id=4607&oid=4184), 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. 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. Appointed monitor/auditor should sign a non-disclosure agreement (http://www2.cch.org.tw/UploadFile/3941/20140521%20CCH%E4%BF%9D%E5%AF%86%E5%88%87%E7%B5%90%E6%9B%B8.pdf) and have personal identifications ready for verification. Acceptable identification documents include PID card, pass port, NIH card or driver's license.
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. 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. 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 2000 system after verification by the staff from the Division of Information Development.