Joint CUHK–NTEC CRMO Newsletter

Issue 5: Feb 2016

Director's Message

Dear Colleagues,

On behalf of all staff at the CUHK-NTEC CRMO, we wish you a happy, healthy and prosperous year of Monkey. In the Chinese calendar, monkey is a clever and vigilant animal which echoes the strategy of CRMO in promoting a conducive environment for conduct of clinical studies with quality and vigilance. As we leave 2015, year of the sheep, it is time to reflect on what we have achieved collectively in the last 12 months. With your commitment and under the stewardship of Iris, our Managing Director and guidance of Dr CK Li, chairman of the Clinical Research Management Committee that provides the overall policy and governance, we have taken great strides in our pursuit of good clinical practice (GCP) to safeguard patient safety and data quality. Here are some of the highlights:

1. In June 2015, we established a Clinical Research Inspection Team consisting of experienced research personnel, nurses and doctors from our CFDA accredited research units (BABE, Cardiology, Endocrinology and Diabetes, Gastroenterology and Hepatology, Oncology and Paediatrics) and members from Clinical Research Ethics Committee (CREC). In this internal quality assurance program, we aim to perform 2 inspections quarterly to share mutual experiences and provide feedback to our research colleagues in their compliance with CUHK-NTEC Standard Operating Procedures (SOPs) and GCP.
2. Since its establishment in June 2013, the CRMO has organized 5 Basic Life Support workshops, supported by Professor David Chung and his team at the KCT Clinical Skill Laboratory; and 2 one-day GCP workshops for investigators and site personnel which are recognized by TransCelerate BioPharma; and luncheon seminars including topics on regulatory approval of clinical trials, writing grant proposals and budget management. We have also put up online modules for training of CRMO SOP and regular online GCP tests with issue of certificates upon completion. We hope you will find these educational materials useful for training of new staff or re-certification of existing staff.
3. With the establishment of the Clinical Research Pharmacy (CRP) in April 2015 and the Quality Assurance and Safety Monitoring subcommittee which consists of members from the HA Quality/Safety Committee, CREC, CRP and Phase 1 Clinical Trial Centre with a mandate to study, review and follow up occurrence of major events, as and when needed, within a clinical research setting, we have now the complete organizational structure to support our colleagues within the CUHK-NTE cluster to design, implement and conduct clinical research studies in full compliance with international standards.
4. One of the highlights was submission by CRMO on behalf of new clinical research units for CFDA accreditation. The inspection by CFDA is expected to take place in 2016. This would enhance our capacity in conducting clinical trials to support new drug registration in China.

It is against this background that we look forward to another fruitful and productive 2016 and wishing our research teams who have submitted for CFDA accreditation every success in their applications.

Happy New Year!

Professor Juliana Chan
Chair Professor of Medicine and Therapeutics,
Director, CUHK-NTEC CRMO

Highlight of Research Unit

Providing best patient-centered care is always the top priority of our colleagues. Dr. Aric Josun HUI, a consultant of Department of Medicine and head of Gastroenterology & Hepatology Research Unit of AHNH, and his team devote themselves in clinical research to seek for better treatment for hepatitis and cost-effective solutions for medical services.

CRMO: Why do you engage in clinical research apart from providing standard medical service?

HUI: As frontline staff, we are aware of the service gaps in our clinical practice. While we may come up with solutions to deal with service gaps, a rigorous scientific approach is needed to evaluate the actual benefits and cost-effectiveness of any proposed solutions. We believe the generation of high quality research with a special focus on the local setting will facilitate the Hospital Authority to deploy its resources in the most effective manner and improve the care we provide to our patients.

CRMO: Can you share with us how you set up your research unit?

HUI: It is difficult to set up a dedicated research unit within the Hospital Authority because of the lack of full-time research staff in frontline hospitals. As such, all research units need to be financially self-supporting through the participation on revenue generating Pharmaceutical studies. It is difficult to find the 'seed money' to kick off the process. Our unit was initially set up by Dr. Nancy Leung Wai-Yee when she was transferred from Prince of Wales Hospital to our unit. She was instrumental in developing our research unit and training our research staff. I am very fortunate to have inherited an excellent research unit from Dr. Leung when she retired in 2012. I am also grateful for Dr. Leung's generosity in sharing her experience in running a research unit.

CRMO: Can you tell us more about your research?

HUI: My current interest is in finding more cost-effective ways of deploying healthcare resources in our local setting. My current projects include the piloting of a nurse-led clinic for dyspepsia, studying the use of instant messaging systems such as SMS to reduce default rates and evaluating the role of upper endoscopy for patients while they are still in the Accident & Emergency Department to identify low risk patients who can be directly discharged.

CRMO: Can you suggest any measures that can empower our colleagues to conduct research?

HUI: Conducting clinical trials in a frontline hospital would be impossible without the support and encouragement of our Hospital Chief Executive (HCE) and Chief of Service (COS) for which I am grateful. In turn, I would like to foster a culture of research in our department and provide assistance to our colleagues who wish to start up research projects. I would like to take this opportunity to thank all the frontline staff, particularly in other departments such as Family Medicine and Accident & Emergency, who have been very supportive of our clinical studies.

Frontline Sharing from Dr. Hui's team

CRMO: What kinds of challenging issues you have faced in clinical research?

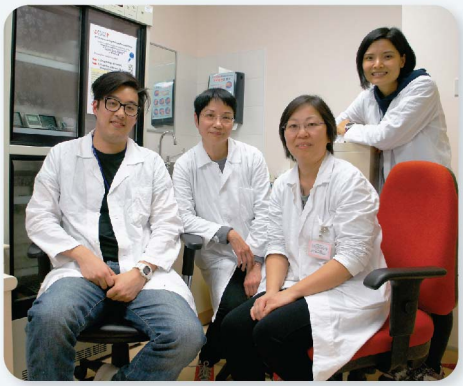
HUI's Team: There are general misunderstanding that complicated protocol is the hurdle for fresh colleagues, but actually this can be overcome by well preparation and guidance by experienced colleagues. Rather, having a clear and full picture of the project is more challenging to them.

Highlight of Research Unit

For the multi-center study, we face lots of pressure from stringent timeline. In Hong Kong, administrative procedures such as ethics committee and regulatory approval take time. Very often we start a study few months later than other global centers. Some of our studies had to be terminated when the recruitment in our site was just started.

CRMO: Clinical trial relies on patient's participation. How do you overcome the barrier of subject recruitment and retention?

HUI's Team: From study initiation to completion, close communication with patients with empathy builds the trust in our relationship. During the informed consent process, we must explain thoroughly and also listen carefully to their concerns. Most of our patients are very cooperative. They are eager to participate in the studies even they are informed that they may be randomized into the placebo group. We encountered a patient showing anxiety distress during blood taking. After talking with him, we found that he worried if blood taking would have negative impact on his health. We comforted him and explained the study procedure again, and let him reconsider whether he would like to continue the study.



CRMO: What are your most memorable moments and how do these memories motivate you to conduct the research?

HUI's Team: Frequent follow-up allows us to have more time to develop good relationship with them. In addition, it is very rewarding when our patients are benefit from the study drug. Personally, we learn a lot about the latest information about hepatitis and treatment approach. We hope our studies could provide better medical service and treatment to our patients.

Tips of the Day

Q1: How often should the research personnel update his/ her CV?

All research personnel must have relevant training(s) when they are carrying clinical research. For clinical healthcare professionals, they are also required to hold a valid practicing certificate issued by an applicable Council (e.g., Medical Council, Nursing Council). All these training records, certificates (if applicable), and relevant qualifications should be reflected and updated in his/her CV timely (or on an annual basis).

Q2: What is the difference between the issue date and the effective date on SOP?

Before the new SOP is effective, it should be issued and circulated to allow familiarization for an ample time. Therefore, the date when SOP is issued is known as issue date should be set before the effective date.

Q3: Can we provide email address rather than the Fax no. in the indemnity letter?

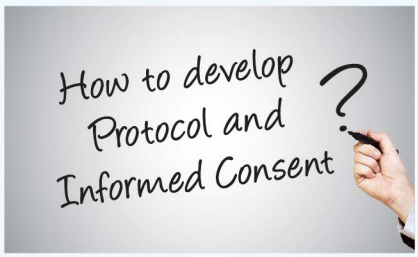
According to the clause 5(b) of indemnity letter, fax no. is needed if any notice is served on other party(ies) for the purpose of that indemnity. Therefore, all involved party(ies) such as Sponsor, HA, and/or University should provide fax no. in the indemnity.

Events

Clinical Trial Management Workshop for Investigator-Sponsored Trials

A series of clinical trial management workshop is being held by the Clinical Research Management Office (CRMO) starting from December, 2015. The first workshop was designed to provide investigators with information and tips on initiating their own academic study with different granting bodies. Thanks to Prof. Juliana Chan and Ms. Iris Chan of the CRMO, the first workshop on investigator-sponsored trials received a warm welcome on 9 Dec. Topics covered included research grant applications, ethics and regulatory requirements, and clinical trial insurance. Additional workshops will be organized in the upcoming months for our seasoned colleagues to share their experience on clinical trial management.

Upcoming Workshops



Two clinical trial management workshops will be held in early 2016. One of them will be focusing on protocol and informed consent development, while the other will be a sharing session on clinical trial budget planning.

In the protocol development workshop, the detailed structure of a GCP compliant protocol will be explained with tips on how to avoid study design and safety reporting pitfalls. The GCP requirements on informed consent forms will also be showcased to avoid approval delays.

In the budget planning workshop, practical experience about study budget calculations and management will be shared.

Please check your email for more information related to the two workshops.

Announcements

New Templates of Indemnity Letter

For sponsored clinical trial, new templates of indemnity letter ("Sponsor/ HA (Jan 2016)" version and "Sponsor/ University/ HA (Jan 2016)" version) is needed to be used if the indemnity is provided on or after 1 Jan 2016 (i.e. the date on the first page of the indemnity). The new HA standard indemnity letters can be downloaded from CREC website http://www.crec.cuhk.edu.hk/download/. Please feel free to contact us for any further enquiry.

Document Storage Solution: External Archival Service

Are you busy in freeing the valuable storage space for the New Year? If you are considering the off-site archival service for clinical trial documents, CRMO can offer a solution! Please visit our website http://www.crmc.med.cuhk.edu.hk/en-us/crmoservice/externalfilearchive.aspx to know more about the external archival service. You can contact us for more information or cost estimation.

Free Clinical Trial Leaflet

Free patient information leaflet that introduces clinical trial, the processes of drug trial, and the frequent asked questions is now available! You can contact us or visit our website http://www.crmc.med.cuhk.edu.hk/CRMCApps/OrderingForm.aspx for more printed copies.

Contact us

Joint CUHK-NTEC Clinical Research Management Office (CRMO)

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香港中文大學－新界東醫院聯網臨床研究統籌處通訊
第五期：2016年2月

總監的話

各位親愛的同事：

本人謹代表中文大學－新界東醫院聯網臨床研究統籌處(CRMO)的同事，恭祝大家猴年生活愉快、身體健康、豐盛連年。在中國的年曆，猴代表了聰明與機警，這與CRMO在推動優質及謹慎的臨床研究環境的策略不謀而合。隨著2015的過去，是總結羊年工作成績的時候；在臨床研究管理委員會主席李志光醫生給予整體政策與管理框架及指導、執行總監陳虹女士的管理和你們的支持之下，在保障病人的安全和數據質素方面，我們向着符合GCP標準的方向跨進向前。以下是部分重點：

1. 臨床研究視察團隊在2015年6月成立，成員包括資深研究人員、護士和醫生，他們來自已獲得國家食品藥品監督管理總局(CFDA)認證的研究單位(生物等效性試驗、心血管、內分泌、消化、腫瘤及兒科)和臨床研究倫理聯席委員會的委員。是項院內品質保證計劃，我們會藉著每季兩次視察，與不同研究單位的同事，對CRMO的標準操作規程(SOP)及GCP交流心得。

2. CRMO自2013年6月成立至今，得到繼昌堂臨床技術學習中心張志偉教授及其團隊的支持，已舉辦了五次成人初級心肺復甦法(BLS)工作坊；另外，我們亦為研究者和相關同事舉辦了兩次GCP工作坊，課程並得到TransCelerate BioPharma認可；還有午間研討會，講題包括臨床研究法規申請、撰寫研究資助計劃書和財務管理等等。我們亦建立了CRMO的SOP線上培訓平台和定期舉辦GCP線上考試，完成後即獲發證書。期盼這些教材有助新舊同事的培訓和獲得有關認證。

3. 臨床研究(藥劑部)於2015年4月成立。此外，醫管局質量 / 安全委員會、臨床研究倫理聯席委員會、臨床研究(藥劑部)及一期臨床研究中心代表組成了臨床研究質量保證和安全監測小組委員會，定期探討、評價和跟進臨床研究出現的重大事故。臨床研究的管理架構已經齊備，為中文大學－新界東醫院聯網的同事就設計、實施和進行符合國際標準的臨床研究提供支援。

4. CRMO代表數個研究單位向CFDA呈交新的認證申請；CFDA的視察會於2016年進行。如是次申請成功，將加強我們藥物臨床試驗的能力，並幫助新藥在中國註冊。

有了這些根基，我們期待2016將會是更成功的豐收年！並祝願已呈交CFDA認證的每一研究團隊申請成功！

新年快樂！

內科及藥物治療學系講座教授
中文大學—新界東醫院聯網　臨床研究統籌處總監
陳重娥教授

卓越研究團隊掠影

提供「病人為本」的醫療服務向來是我們各醫護同事的首要任務；大埔那打素醫院內科顧問醫生暨腸胃及肝臟科研究單位主管許祖紳醫生及其研究團隊，致力透過臨床研究為肝炎患者尋求更好的治療，並為醫療服務尋找更具經濟效益的的解決方案。

CRMO：除了提供常規醫療服務外，你為何從事臨床試驗？

許醫生：作為一個醫療服務的前線工作者，我們比較容易注意到醫療服務上的不足之處。雖然我們可能會想出這些不足之處的解決方案，但仍有必要以一個嚴謹的科學方法，評估所提出的解決方案的實際利益和經濟效益。我們相信以本地情況為研究目標的高質素研究，能協助醫管局以最有效的方式調配資源，改善我們為病人提供的護理。

CRMO：能否分享一下你是如何開展第一項臨床試驗？

許醫生：醫管局的前線醫院一直缺乏全職的的臨床研究人員，在這種環境下要設立專門的研究單位是充滿挑戰。所有臨床研究單位需透過參與藥物研究而自負盈虧，但最初獲得研究經費往往困難重重。我們的成立有賴當時從威爾斯親王醫院調來的梁慧儀醫生促成。梁醫生在成立研究單位及研究人員培訓等方面給予很大的幫助。在她2012年退休時，我很榮幸繼承了這支優秀的研究隊伍。我衷心感激梁醫生在帶領研究隊伍上無私地分享她的經驗。

CRMO：可否和大家分享多些你的研究方向？

許醫生：我近期的研究針對我們醫院的資源調配方面，尋找更具經濟效益的解決方案。目前的項目包括為消化不良病人成立由護士主導的診所試點、利用即時通訊系統(例如:SMS)提醒病人覆診以減低覆診缺席率、及評估在意外及急救部門(A&E)為病人進行胃鏡檢查以診斷哪些為無須住院的低風險病人。

CRMO：可否建議一些措施能幫助同事進行臨床研究？

許醫生：如沒有醫院行政總監和部門主管的支持和鼓勵，在前線醫院開展臨床研究實是遙不可及，在此我非常感激他們的幫忙。在內科部，我很希望能推動臨床研究的文化，及為想開展研究的同事提供協助。最後，我想藉此機會感謝一直支持我們的所有前線人員(特別是家庭醫學部及意外及急救部)。

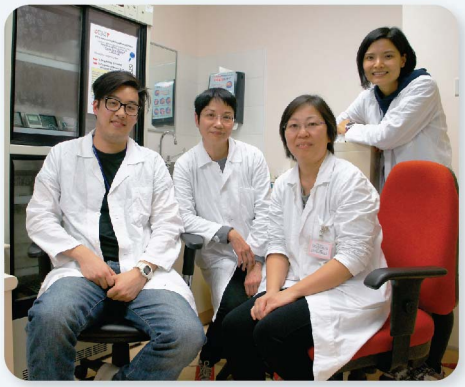
腸胃及肝臟科研究團隊分享

CRMO：在進行臨床研究時，你們面對哪些挑戰？

研究團隊：一般人誤解以為經驗尚淺的同事不能處理複雜的臨床研究。然而充足的預備及資深同事的指導往往能解決這些困難。相對來說，對研究計劃有清晰和完整的理解才是他們的挑戰。

對於多中心的研究，緊迫的時間表給予我們不少壓力。在香港，申請臨床研究道德倫理和其他法規的批准需時，我們通常較其他地區的中心起步遲幾個月；有些臨床研究，當我們剛開始招募，已經收到停止招募的通告了。

卓越研究團隊掠影



CRMO：臨床試驗有賴病人的參與。你如何克服招募及留住受試者的困難?

研究團隊：在整個研究過程，緊密的溝通和對病人的體諒能為我們建立互信的關係。在整個知情同意過程中，我們會向他們仔細解釋和細心聆聽他們的顧慮。我們大部份的病人都非常合作；即使被告知有可能因應隨機分配而被分派到對照組時，他們仍欣然接受，樂於參與臨床研究。

曾經，有一位病人在抽血過程中表現得很焦慮。經了解後，他表示擔心抽血會影響他的健康。我們安慰他並再次解釋研究所涉及的過程，着他重新考慮是否願意繼續參與研究。

CRMO：在你們的工作環境，有哪些值得緬懷的片段？這些美好的片段如何促進你們對工作的熱忱？

研究團隊：在頻密的覆診中，我們有更多時間與病人溝通和建立良好關係。目睹病人從研究藥物中得到益處是我們最大的動力。就個人而言，因着臨床研究，我們可以獲悉肝炎的最新資訊和治療方法。我們期盼進行臨床研究能為病人提供更佳的醫療服務和治療。

每日提要

探討問題 (1) ：研究人員相隔多久需要更新他/ 她的個人履歷？

所有研究人員進行臨床研究時，必須具備相關的培訓。醫療專職人員須持有由相關委員會(例如：醫務委員會、護士管理局等)簽發的有效執業證書。所有的培訓記錄、證書(如適用)及相關的資格應適時更新並顯示在個人履歷上(或至少每年更新一次)。

探討問題 (2) ：標準操作規程(SOP)的發佈日期和生效日期有何不同？

新/更新的SOP在生效之前需發佈讓同事知悉及作出培訓；因此，SOP發佈日期應該劃定在生效日期之前。

探討問題 (3) ：可否在醫管局的保證書(Indemnity Letter)提供電郵地址以代替傳真號碼？

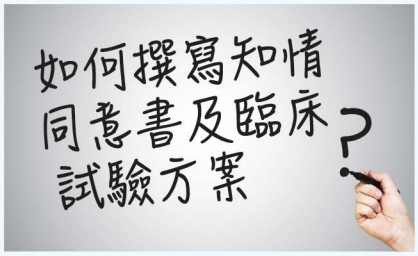
根據 Indemnity Letter 條款5(b)，各方如有任何關於保證書的內容通知對方，須以傳真聯絡。故此，所有參與的機構包括申辦者、醫管局、和 / 或大學必須在保證書內提供傳真號碼。

活動剪影

研究者擬定的臨床研究計劃(IST)工作坊

臨床研究統籌處(CRMO)舉辦一系列的臨床研究管理工作坊，已於2015年12月展開。首個工作坊為開展個人學術研究的研究者提供不同資助機構的資訊與申請竅門；是次內容包括申請研究資助、臨床研究倫理和相關法規批准的要求及臨床試驗保險等。感謝臨床研究統籌處總監陳重娥教授和執行總監陳虹女士的適切講解，當日參與的同事反應熱烈。在未來數月CRMO會繼續舉辦IST系列工作坊，邀請具有豐富臨床研究經驗的同事和大家分享他們的管理心得。

工作坊預告



CRMO計劃於2016年初舉行兩場臨床研究管理系列工作坊。其一是聚焦於臨床試驗方案和知情同意書的撰寫；另一是計劃臨床研究預算的分享會。

在臨床試驗方案撰寫工作坊，我們將會詳細講解符合GCP臨床試驗方案的結構及提供秘訣，避免在設計研究和報告安全事件遇上陷阱，及展示知情同意書範本，減低申請的延誤。

至於預算計劃工作坊，我們將會分享預算研究經費和管理的實際情況。有關以上兩個工作坊的詳情，請留意電郵公佈。

通告

保證書(Indemnity Letter)新範本

在2016年1月1日或之後，申辦者贊助的臨床研究使用的保證書，必須採用新的範本「Sponsor / HA (Jan 2016)」版本和「Sponsor / University / HA (Jan 2016)」版本。更新了的範本可在CREC網頁 http://www.crec.cuhk.edu.hk/download/ 下載，如有任何進一步的查詢，歡迎聯絡我們。

文件儲存空間的解決方案－院外文件儲存服務

在新的一年，你是否正為寶貴的儲存空間考慮院外臨床研究文件儲存服務？我們可替您安排！詳情請參考www.crmc.med.cuhk.edu.hk/en-us/crmoservice/externalfilearchive.aspx。如需其他資料或詳細的費用預算，歡迎與我們聯絡。

免費臨床試驗小冊子

為協助大家和受試者解釋臨床試驗，CRMO已就臨床試驗的基本背景、藥物臨床試驗的程序及受試者的常見問題設計了一本小冊子。歡迎各臨床研究人員聯絡我們或於以下網頁http://www.crmc.med.cuhk.edu.hk/CRMCApps/OrderingForm.aspx登記，索取有關小冊子。

聯絡方法

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