國立臺灣師範大學
National Taiwan Normal University

FERCAP 2014 觀察員報告

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FERCAP的意涵

- The **Forum for Ethical Review Committees in the Asian and Western Pacific Region (FERCAP)** was conceived in Bangkok, Thailand on 12 January. http://www.fercap-sidcer.org/whatsfercap.php
- FERCAP is a project of the **World Health Organization (WHO) Special Training and Research Programme in Tropical Diseases (TDR)** and it is a regional forum under the umbrella of the **Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)**. http://www.fercap-sidcer.org/whatsfercap.php
- **SIDCER Recognition** for every three years

認證查核對象:中山醫學大學附設醫院

http://www.csh.org.tw/irb/Index.htm

Surveyors & Observers/Trainees

* 簡報中所有照片均由TAIRB提供，謹此致謝!

FERCAP會前會(2014/06/30)
培訓、溝通與分工

- **FERCAP IRB Audit Training for Continuous Quality Improvement of IRB Operations**
- **Training Objectives**
  - A. To conduct periodic evaluation of the quality of IRB operations
    - To review existing written Standard Operating Procedures (SOP) and adherence to these procedures
    - To assess compliance to international, national and local standards
  - B. To make appropriate recommendations based on evidence
  - C. To develop an internal quality assurance program towards continuous quality improvement of IRB operations

10:30-11:15	Improving review of different types of protocols (Drugs, Medical Device, Biologics) Hsiang Ning Luk
11:15-11:45	Indicators for performance of IRB members and staff Shih Li Su (Changhua IRB Representative)
11:45- 12:15	Evaluating quality of protocol review (Use of Pareto chart, etc.) Peywen Jeng
12:15-13:30	Lunch
13:30-14:00	Root cause analysis Hsiang Ning Luk
14:00-14:30	Update on international guidelines: Implication on IRB SOPs Cristina E. Torres
14:30-15:15	Continuous quality improvement of IRBs: Baseline and audit assessment points Cristina E. Torres
15:15-15:30	Break
15:30-16:15	Quality assessment of board meetings Cristina Torres
16:15-16:45	Evaluating quality of continuing review Cristina Torres
16:45-17:15	Auditing IRB documentation Cristina Torres
17:15-17:45	Developing templates for better informed consent forms Cristina Torres
17:45-18:45	Working Groups Practical I: Preparing for a Site Visit Preparing the Survey Plan ▪ Grouping the surveyors and trainees ▪ Assigning responsibilities to the survey groups ▪ Selection of persons to be interviewed ▪ Selection of protocols for review

7/4 參觀+訪談 +閱讀資料+討論

Agenda of FERCAP Site Visit at Chung Shan Medical Hospital
1st Institutional Review Board / 2nd Institutional Review Board
July 4 (Fri.) ~ July 6 (Sun.), 2014.

Day 1: July 4 (Fri.)

Time	Activities	Venue
08:30~09:00	Departure from the Hotel to the Ethics Committee Site	
09:00~10:30	Opening Meeting	10F conference room (Administrative building)
10:30~11:30	Visit IRB Office	IRB Office (17F., Ruchuan Building)
11:30~12:30	Lunch	1704 conference room (17F., Ruchuan Building)
12:30~14:00	Member interview	1702/1703 conference room (17F., Ruchuan Building)
14:00~16:00	Review of protocols	1704 conference room (17F., Ruchuan Building)
16:00~17:00	Summary of the Day's Findings	
17:00~	Departure from the Ethics Committee Site to the Hotel (Dinner Box- Take Out)	

7/5 旁聽審查會
+閱讀資料+討論+晚宴

Day 2: July 5 (Sat.)

Time	Activities	
08:30~09:00	Departure from the Hotel to the Ethics Committee Site	
09:00~10:00	Review of protocols	an Building)
10:00~12:00	Observe Board meeting	10F conference room (Administrative building)
12:00~13:00	Lunch	1704 conference room (17F., Ruchuan Building)
13:00~16:00	Review of protocols	1704 conference room (17F., Ruchuan Building)
16:00~17:00	Summary of the Day's Findings	
17:00~20:00	Dinner	蓮園展華花園會館 (Zhanhua-Garden)
20:00~	Departure from the Ethics Committee Site to the Hotel	

7/6 討論+撰寫報告 +總結報告與IRB回應 +檢討回饋

Day 3: July 6 (Sun.)

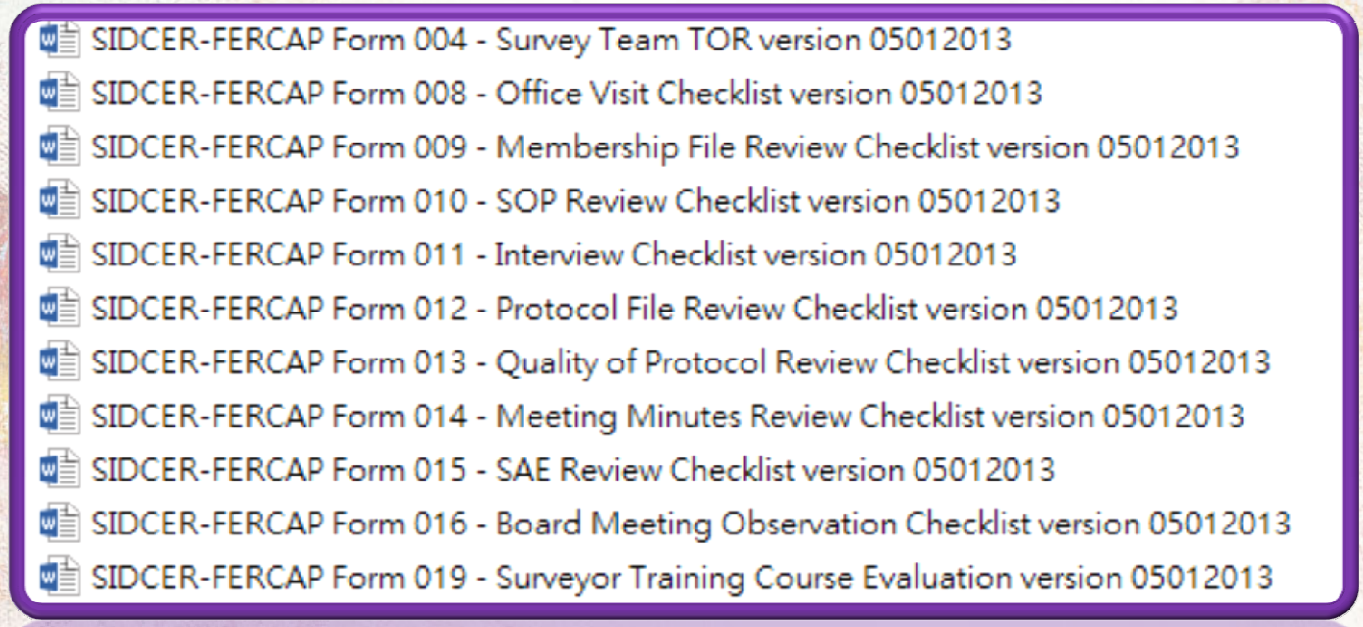
Time	Activities	Venue
08:30~09:00	Departure from the Hotel to the Ethics Committee Site	
09:00~12:00	Summary of findings and observations	1704 conference room (17F., Ruchuan Building)
12:00~13:00	Lunch	
13:00~14:00	Closing meeting	
14:00~15:00	Reports and follow-up procedures	
15:00~	Awarding of the SIDCER Training Certificate and Close of the Course	10F conference room (Administrative building)

FERCAP認證查核的目的

- SIDCER provides the international community with not only a means to build in-country **human participant protection programs**, but also a way to measure and provide accountability regarding **the quality and effectiveness** of ethical review worldwide. http://www.fercap-sidcer.org/recog.php

FERCAP認證查核的依據

- International Guidelines
- Taiwan Regulations and Guidelines
- SIDCER Survey SOPs



FERCAP認證查核的方法

- 聆聽受評單位**簡報**
- 參訪受評單位**辦公室**
- **訪談**委員與行政人員
- 旁聽**Board meeting**
- 閱覽**protocols**
- **閱覽**檔案、通訊與會議記錄
- 檢核受評單位所訂**SOP**及其執行情形
- 訪評成員與受評單位**溝通**會議

FERCAP認證查核的層面及其標準

I. Structure and composition
II. Adherence to specific policies
III. Completeness of review procedures
IV. After review process
V. Documentation and archiving

接續五頁的分述均引自http://www.fercap-sidcer.org/recog.php

Standard I. STRUCTURE AND COMPOSITION
Structure, composition and skills of the EC/IRB and staff are appropriate to the amount and nature of research reviewed

e.g., **1.1. MEMBERSHIP REQUIREMENTS**

- 1.1.1. Members: at least 5
- 1.1.2. Gender: Balance
- 1.1.3. Experience and knowledge: balance in ethics, science and social science (alternatives to cover the topic of review should be in place)
- 1.1.4. Non-scientific or lay person
- 1.1.5. Non-affiliated person (independent of the institution/research site)
- 1.1.6. Terms and conditions of appointment, including policy and duration of appointment, disqualification, resignation and replacement procedures

Standard II: ADHERENCE TO SPECIFIC POLICIES EC/IRB has appropriate management and operational procedures for optimal and systematic conduct of ethical review

e.g., **2.2. AVAILABILITY OF STANDARD OPERATING PROCEDURES (SOPs)** The EC/IRB should have a written SOP with which they comply. The reasons for any non-compliance should be stated.

2.3. AREAS AND FUNCTIONS COVERED BY THE SOPs

SOPs should include, but not be limited to:

- Normal review process,
- Review of resubmitted,
- Amended,
- Continuous protocol review
- Confidentiality,
- Informed consent review, and.
- Expedited reviewed.

Standard III: COMPLETENESS OF ITS REVIEW PROCESS

EC/IRB review protocols and its supporting documents in a timely fashion according to an established procedure to protect the interest of research participants

e.g., **3.4. ELEMENTS OF REVIEW**

- The process and functions of members and staff in this process should be clearly indicated. EC/IRB should state clearly what elements they review in a protocol. Review element should include: **value of research, scientific design and conduct, ethics (risk, benefit, informed consent documents and processes, care and selection of participants etc.).**

Standard IV: AFTER REVIEW PROCESS

EC/IRB should adequately and effectively communicate its decision to investigators

4.1. COMMUNICATING DECISION

EC/IRB should have an effective and timely way of communicating a decision.

Where protocol approval was denied by the EC/IRB, reasons should be clearly stated. If provisional approval is given areas that need be re-worked should be clearly stated. EC/IRB should have and issue approval/disapproval letters with the conditions of approval or reasons for disapproval clearly stated.

The IRB should have and issue suspension/termination letters with the conditions of lifting suspension and the reasons for suspension or termination clearly stated.

Standard V: DOCUMENTATION AND ARCHIVING

EC/IRB systematically documents and archives its activities for a good time period

5.1. EC/IRB DOCUMENTATION AND ARCHIVING

All protocols with a complete set of its supporting materials are maintained by the EC in a file or database till at least 3 years after the end of the study

All documentations on pertinent discussions and decisions on protocols and communication of the EC/IRB should be properly filed and archived for easy access.

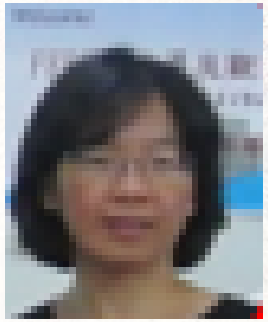
All documents pertinent to effective function of the EC including its SOPs, constitutions, regular annual reports, national and international guidelines etc. should be properly kept.

A retrieval procedure should be indicated and complied with. The minimum period of archive should also be stated and complied with.

參訪心得與反思: 李琪明

- 見樹又見林的研究倫理拼圖之旅
- 學術研究應是個人與群體的共同成就與責任
- 理解國內外研究倫理指引與法規與爭議處
- 跨領域溝通對話與達致共識的歷程
- 強調行政效能與支援系統(人力物力財力)品質
- 堅持學術自由與研究倫理的平衡
- 辯證性反思認證查核的目的及其限制
- 再思不同專業領域研究倫理實踐轉化的同與異

參訪心得與反思: 田秀蘭



- 填不完的**表格**
- IRB成員得有足夠**經驗**
- 擔任主委及秘書，**可不輕鬆**
- 得懂得醫學界研究文化及**專有名詞**
- 擔任 IRB委員，得投入相當**時間心力**
- 秘書及委員得有足夠的**邏輯能力**
- 倫理委員會如何**忠於倫理**

填不完的表格(1/2)

- Form 004: Survey Team TOR (Terms of Reference)
- Form 008: Office Visit Checklist (辦公室硬體環境參訪，含設備齊全、隱密性等等）
- Form 009: Form 009: Membership File Review Checklist（IRB 委員會組成之成員，含職務、學歷、專長等基本資料）
- Form 010: SOP Review Checklist (version)
- Form 011: Interview Checklist

填不完的表格(2/2)

- Form 012: Protocol File Review Checklist
- Form 013: Quality of Protocol Review Checklist
- Form 014: Meeting Minutes Review Checklist
- Form 015: SAE Report Review Checklist
- Form 016: Board Meeting Observation Checklist
- FERCAP Form 019: Surveyor Training Course Evaluation

IRB成員得有足夠經驗

- Form 011: Interview Checklist
- 接受訪談，得有心理準備
- 沒有經驗，還真回答不出什麼內容
- 說明自己在委員會中的任務內容以及所承擔的責任
- 問題內容，包括如何進入IRB的，IRB主委如何運作整個團隊等等
- 承擔這樣的責任或出席會議，協助審查等等，是否會增加個人的負擔，讓個人覺得疲累？

擔任主委及秘書，可不輕鬆

- 主委及秘書，就是整個團隊的核心。
- 在參訪過程中，由非正式的互動中，可以觀察到主委及執行秘書的處事風格。
- 從平日對各個計畫的狀況，到審查大會的主持，可以看出主委對這些案件的投注，尤其是特別需要注意的案件。

得懂得醫學界研究文化及專有名詞

- No. of arms: 4（四個分支，亦即四個分組實驗操控，四種不同的藥物或實驗處遇方式）
- SAE (Serious Aversive Event)
- Double Blind RCT vs. Single blind RCT

擔任 IRB委員，得投入相當時間心力

- 協助審查案件，每月負擔約2-3件，
- 每月得出席審查大會，因此所付出之時間頗多。
- 每年必需參與一定時數之繼續教育訓練。
- 審查的進行不得拖延，否則會形成委員會的麻煩。
- 從收案到回覆，從回覆已經收案到審查結果的通知，有一定時間期限規定，在審查規則中均有明定。

秘書及委員得有足夠的邏輯能力

- 審查案件的分類及審查程序，不得搞錯。
- 審查過程，依分類結果進行，收費及程序也不得搞混。
- 紙本或線上審查，各有利弊。就如同 TSSCI 期刊的編輯程序，邏輯、時間及專業的能力，同樣重要。

倫理委員會如何忠於倫理

- 有人認為 IRB 是研究的一種戕害，阻撓個人在研究進行的順利及便利、適當。
- 光是填一堆表格，就很麻煩？
- 整個過程，究竟為個案（研究參與者）提供了多少的保護？
- 遵守倫理的人，就是遵守；不遵守倫理的人，自然還是有辦法找方便之路？IRB究竟能發揮多少功能，值得討論，並找出真能發揮功能的運作辦法。

國立臺灣師範大學研究倫理中心

研發處 / 企劃組 / 研究推動組 / 產學合作組 / 貴重儀器中心 / 創新育成中心 / 研究倫理中心

THANK YOU

研究倫理中心