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管制文件訂修廢紀錄表
Record of Composition and Revisions of Controlled Documents

文件編號 Document Number	IRB-本會-工作常規-2002 IRB-Regulations of Operation-2002	文件名稱 Title	第一/二人體研究倫理審查委員會教育訓練管理程序書 SOP for Education and Training of the First/Second IRB Committees
訂定單位 Composed by	第一/二人體研究倫理審查委員會 The First/Second IRB Committees	機密等級 Level of Confidentiality	■普通 □密件 □極機密 ■Unclassified □Confidential □Highly Confidential
適用單位 Applied to	□全院 □All units in the hospital ■其他，請註明：第一/二人體研究倫理審查委員會 ■Other (Please specify): The First/Second IRB Committees		

版次 Version	頁數 No. Pages	文件修訂摘要 Summary of Revisions of the Document	實施日期 Date of Implementation
A	5	新訂。 Newly composed	20140519
B	5	1. 更改文件名稱。 1. The title of the document was revised. 2. 由人體試驗委員會標準作業程序 5.4 版轉換成此版本。 2. This version was converted from “Version 5.4 of the Standard Operating Procedure of the Human Research Committee.”	20141125
C	5	1. 原「人體試驗委員會」更名為「第一/二人體研究倫理審查委員會」。 1. The original “Human Research Committee” was renamed “The First/Second IRB Committees”. 2. 修改 5.5.3：新增續聘委員轉調人體研究倫理審查委員會者職前訓練說明。 2. Revised item 5.5.3: Added the requirement of orientation for new IRB members.	20160318

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版次 Version	頁數 No. Pages	文件修訂摘要 Summary of Revisions of the Document	實施日期 Date of Implementation
D	5	1. 修改 5.1 流程圖之相關文件。 1. Revised the list of relevant documents in item 5.1 Flow Chart. 2. 修改 5.2.1 訓練主題：新增「審查會之標準作業程序」。 2. Revised item 5.2.1 Training Topics: Added “IRB Standard Operating Procedures.” 3. 修改 5.2.1.6 為「審查會之標準作業程序」。 3. Revised item 5.2.1.6 into “IRB Standard Operating Procedures.” 4. 修改 5.5.2 之委員教育訓練主題及承辦人教育訓練時數。 4. Revised the topics of training for IRB members and the hours of training for staff members in item 5.5.2. 5. 修改 5.5.4：新增線上教育訓練來源及時數限制。 5. Revised item 5.5.4: Added the sources for online training and the limitation for the hours of online training. 6. 修改 5.7.1 提供訓練證明：刪除「影本」2 字。 6. Revised item 5.7.1 concerning submission of proof of training: Deleted the word “photocopies.” 7. 刪除原附件 6.1 委員教育訓練記錄檔案夾及原 6.2 工作人員教育訓練記錄檔案夾。 7. Deleted the original appendix 6.1 “Portfolio of training records of IRB members” and the original appendix 6.2 “Portfolio of training records of staff members.”	20170709

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版次 Version	頁數 No. Pages	文件修訂摘要 Summary of Revisions of the Document	實施日期 Date of Implementation
E	9	1. 更新參考文件 3.1 為 2011 年；修改參考文件 3.2 為「International Conference on Harmonization of Good Clinical Practice Guidelines (ICH GCP), 2016」。 1. Updated the year of reference 3.1 to 2011; Revised reference 3.2 into “International Conference on Harmonization of Good Clinical Practice Guidelines (ICH GCP), 2016.” 2. 依據 FERCAP 國際訪視之建議，新增參考文件 3.3「The Council for International Organizations of Medical Sciences (CIOMS), International ethical guidelines for health-related research involving humans, 2016」。 2 Following the suggestions made by site-visit reviewers of FERCAP, reference 3.3 “The Council for International Organizations of Medical Sciences (CIOMS), International ethical guidelines for health-related research involving humans, 2016” was added. 3. 依據 FERCAP 國際訪視之建議，增加 5.2.1.7 受試者之風險/利益評估及增加 5.2.1.8 各類型計畫案之審查重點(包含易受傷害族群、修正案、追蹤審查報告等)。 3 Following the suggestions made by site-visit reviewers of FERCAP, item 5.2.1.7 “Risk/Benefit Assessment for Clinical Trial Subjects” was added. And item 5.2.18 “Key points in reviewing all types of protocols (including those involving vulnerable subjects, amended protocols, reports of continuing review, etc.)” was added.	20181026

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版次 Version	頁數 No. Pages	文件修訂摘要 Summary of Revisions of the Document	實施日期 Date of Implementation
E	9	4. 修改 5.4.1.2 為「承辦人員依照院內規定提出申請，並送請院內相關單位及院部長官批核同意」。 4. Revised item 5.4.1.2 to be “Staff members shall submit application forms for approval from relevant units and hospital superiors.”	20181026
F	9	1. 新增 5.2.1.9 有關披露財務的利益衝突與責任的教育訓練。 1. Added item 5.2.1.9 Educational training on the disclosure of financial conflicts of interest and responsibilities. 2. 新增 5.5.5 每位研究團隊成員於執行研究計畫前至少須接受 1 小時以上之利益衝突管理的教育訓練，此後應每 3 年一次 2. Added item 5.5.5 Before execution of the research project, each research personnel must receive at least 1 hour of educational training on conflicts of interest, and followed up with repeated trainings at no less than once every three years thereafter.	20190527
G	9	1. 5.5.4 增加「疫情期間不受此限」之說明。 1. Added the description "not subject to this restriction during pandemic" in item 5.5.4.	20210528

訂修廢 Composed/Revised/Deleted	審核 Reviewed	核准 Approved

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本文件已經權責主管正式核准，
核章紀錄之正本儲放於 SOP 管理中心

※管制文件不得擅自塗改及做記號並禁止影印。
※本文件以 KM 系統為最新版本，紙本發行需經 SOP 管理中心核章，嚴禁自行列印。
※Changing, marking, or copying controlled documents without permission is prohibited.
※The latest version of this document in the Knowledge Management System (KMS) takes precedence. Distribution of hard copies of this document must be approved and stamped by the SOP Administrative Center. Copying without permission is strictly prohibited.

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管制文件訂修廢會審單
Review Form of Composition and Revisions of Controlled Documents

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會辦單位 Processing Unit	審查意見 Review Comments	會辦單位主管 Head of Processing Unit
	無跨部科會審需求。 There is no need for review by other departments or divisions.	

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※請各會辦單位主管惠賜審查意見後核章，必要時得直接與訂定單位協商。

※The head of each processing unit is advised to provide comments before signing/stamping to approve. If needed, it is recommended that the head of each processing unit discuss with the unit that made the SOP.

1.目的

爲提升第一/二人體研究倫理審查委員會委員、工作人員與研究人員對人體研究之科學、倫理及法規等專業知能，須辦理教育訓練或研討會，特制訂本管理程序書。

1. Purpose

The purpose of this SOP is to manage the organization of training courses and conferences in order to enhance professional knowledge of IRB members, staff, and research personnel in the science, ethics, and regulations regarding human research and clinical trials.

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2.適用範圍

凡本院第一/二人體研究倫理審查委員會之委員、承辦人員與研究人員舉辦教育訓練之管理均適用本管理程序書。

2. Scope

This SOP applies to the management of education and training for IRB members, staff members, and research personnel of TCVGH.

3.參考文件

3. References

3.1 World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2011.

3.2 International Conference on Harmonization of Good Clinical Practice Guidelines (ICH GCP), 2016.

3.3 The Council for International Organizations of Medical Sciences (CIOMS), International ethical guidelines for health-related research involving humans, 2016.

4.名詞定義

4. Definitions

4.1 研討會

來自各組織的個人或代表，依共同的興趣為主題，開會討論研究。

4.1 Conference

Individuals or representatives from various organizations convene to discuss and investigate topics of common interests.

4.2 會議

由二人以上共同討論如何達成一致的協議。

4.2 Meeting

Two or more individuals meet to discuss how to reach a consensus on a certain issue.

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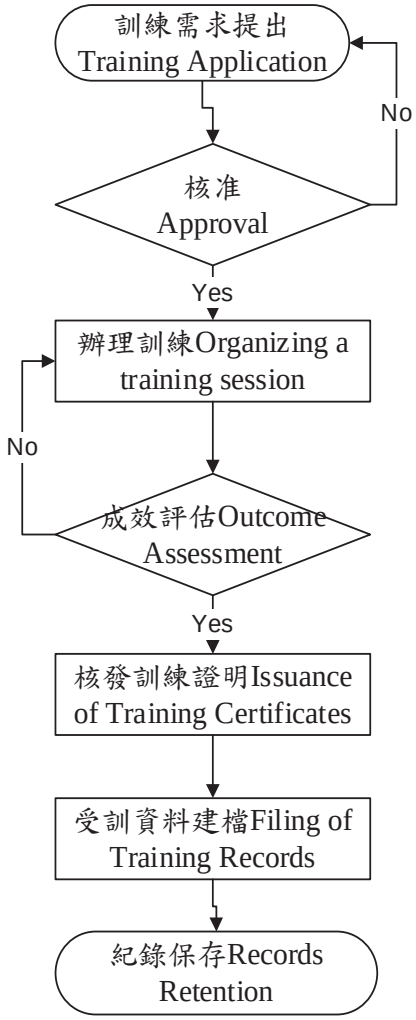
5.作業內容

5. Procedure

5.1 第一/二人體研究倫理審查委員會教育訓練流程圖

5.1 Flow Chart of IRB Education and Training

流程 Flow Chart	權責 Responsible Personnel	相關文件 Relevant Documents
	(副)主任委員/執行秘書 Chair or Vice Chair / Executive Secretary 院部長官/主任委員 TCVGH Superiors / Chair 工作人員 Staff members 院內外承辦單位 TCVGH/Non-TCVGH Organizer 院內外承辦單位 TCVGH/Non-TCVGH Organizer 承辦人員 Staff members 承辦人員 Staff members	訓練課程相關申請表單 Training Application Forms 簽文 Approval Documents 申請表單/簽到單/領據 Application Forms/Sign-in Sheet/Receipts 訓練證明書 Training Certificates 訓練證明書 Training Certificates 訓練證明書 Training Certificates

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5.2 訓練需求提出

5.2 Training Application

5.2.1 訓練主題

爲提升第一/二人體研究倫理審查委員會委員、工作人員與研究人員對人體研究之科學、倫理、法規及審查會之標準作業程序等專業知能，辦理教育訓練或研討會之訓練主題可涵蓋：

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5.2.1 Training Topics

In order to enhance professional knowledge of IRB members, staff, and research personnel in the science, ethics, and regulations regarding human research and clinical trials, topics of training courses and conferences may cover the following areas:

5.2.1.1 優良臨床試驗規範和準則。

5.2.1.1 Regulations and guidance on good clinical practice

5.2.1.2 貝爾蒙特報告與赫爾辛基宣言。

5.2.1.2 Belmont Report and Declaration of Helsinki

5.2.1.3 倫理議題。

5.2.1.3 Ethical issues

5.2.1.4 相關法律。

5.2.1.4 Relevant laws and regulations

5.2.1.5 相關科學、技術、環境、健康和安全方面的發展。

5.2.1.5Relevant development in the aspects of science, technology, environment, health, and safety

5.2.1.6 審查會之標準作業程序。

5.2.1.6 IRB Standard Operating Procedures

5.2.1.7 受試者之風險/利益评估。

5.2.1.7 Risk/Benefit assessment for clinical trial subjects

5.2.1.8 各類型計畫案之審查重點(包含易受傷害族群、修正案、追蹤審查報告等)。

5.2.1.8 Key points in reviewing all types of protocols (including those involving vulnerable subjects, amended protocols, reports of continuing review, etc.)

5.2.1.9 有關披露財務的利益衝突與責任的教育訓練。

5.2.1.9 Educational training on the disclosure of financial conflicts of interest and responsibilities.

5.2.2 訓練種類

5.2.2 Types of Training by Organizers

5.2.2.1 本會主辦或與其他單位協辦、合辦。

5.2.2.1 Training organized by TCVGH or co-organized by TCVGH with other organizations

5.2.2.2 院外機構舉辦之訓練。

5.2.2.2 Training organized by non-TCVGH organizations

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5.3 核准

5.3 Approval

5.3.1 舉辦相關院內外教育訓練，需簽陳院部長官核准同意。

5.3.1 Requests for organizing training within or outside TCVGH shall be submitted to and approved by TCVGH superiors in writing.

5.3.2 奉准（派）公假參與相關院內外教育訓練，需簽陳院部長官核准同意。

5.3.2 Requests for taking official leave to attend training sessions within or outside TCVGH shall be submitted to and approved by TCVGH superiors in writing.

5.4 辦理訓練

5.4 Organizing Training Sessions

5.4.1 秘書處視委員、承辦人員和相關研究人員之需求，辦理相關

教育訓練課程。

5.4.1 The IRB Secretariat may organize relevant training sessions based on the needs of IRB members, staff, or research personnel.

5.4.1.1 秘書處將規劃課程內容、上課時間、講師名單以及預借活動場地，並公告相關資訊。

5.4.1.1 The Secretariat shall announce the information regarding the content, time, instructor(s), and booked venue of the training sessions.

5.4.1.2 承辦人員依照院內規定提出申請，並送請院內相關單位及院部長官批核同意。

5.4.1.2 Staff members shall fill out and submit application forms for approval from relevant units and hospital superiors.

5.4.1.3 承辦人員於課程前需確認參與學員人數，並視需要訂定餐點及印製講義。

5.4.1.3 Staff members shall confirm the number of participants before a training session starts, and order meals and print handouts for participants if needed.

5.4.1.4 承辦人員需備齊簡報筆、相機、簽到單、講師領據等文件，以便訓練課程當天使用。

5.4.1.4 Staff members shall prepare a presentation pointer/clicker, a camera, a sign-in sheet, and the receipt for the instructor's honorarium on the day of the training session.

5.4.2 對於與其他單位合辦之教育訓練課程，承辦人員將訓練課程資訊公佈於本會網站，並通知本會所有委員知曉。

5.4.2 Regarding training sessions co-organized by TCVGH and other organizations, staff members shall announce relevant information on the IRB website and notify all IRB members of the events.

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5.5 成效評估

5.5 Outcome Assessment

5.5.1 各項訓練課程得依承辦單位之規定以考試、問卷等方式進行成效評估，符合資格者得發予「訓練證明書」。

5.5.1 The outcome of training sessions may be assessed by administering tests or requiring participants to fill out questionnaires depending on the guidelines set by the organizers of the training sessions. Training Certificates may be issued to qualified participants.

5.5.2 委員每年應接受至少 6 小時以上「倫理」、「法律」、「審查會之標準作業程序」及其他臨床試驗相關之教育訓練，承辦人員應接受 6 小時以上之上述教育訓練，並取得相關證明文件影本供本會備查。

5.5.2 IRB members shall complete at least 6 hours of training each year on the topics of ethics, laws and regulations, IRB Standard Operating Procedures, and other topics related to clinical trials. Staff members shall complete at least 6 hours of above-mentioned training. IRB members and staff shall submit photocopies of proof of participation in relevant training to the IRB for recordation.

5.5.3 新進委員應接受職前教育（參與 1 次大會審查，並由現任資深委員諮詢、輔導 2 件新案審查）；若續聘委員轉調本院第一/二人體研究倫理審查委員會者不在此限。

5.5.3 A new IRB member shall complete the orientation before the term of appointment (the orientation consists of attending an IRB board meeting and being guided by a current senior member to review two new protocols). An IRB member who is newly appointed on one IRB committee and has served on the other IRB committee previously does not have to go through the orientation process again.

5.5.4 計畫主持人、共同主持人、協同主持人及其他研究人員之教育訓練時數，由大會另訂定之。線上教育訓練時數僅限本院

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數位學習課程，且不得超過總時數之百分之五十(疫情期間不受此限)。

5.5.4 The required training hours for principal investigators, co-investigators, sub-investigators and other researchers are specified in another regulation by the IRB. Online training will be recognized only if it is provided by TCVGH e-learning. The hours of online training shall not exceed 50% of the total hours of training (not subject to this restriction during pandemic).

5.5.5 每位研究團隊成員於執行研究計畫前至少須接受 1 小時以上之利益衝突管理的教育訓練，此後應每 3 年一次。

5.5.5 Before execution of the research project, each research personnel must receive at least 1 hour of educational training on conflicts of interest, and followed up with repeated trainings at no less than once every three years thereafter.

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5.6 核發訓練證明

課程結束後，院內外辦理課程之承辦單位將依其規定核發書面或電子訓練證明書。

5.6 Issuance of Training Certificates

On completion of a training session, the TCVGH or non-TCVGH organizer of the session shall issue training certificates in paper or electronic forms.

5.7 受訓資料建檔

5.7 Filing of Training Records

5.7.1 委員及承辦人員需提供訓練證明送交秘書處。

5.7.1 IRB members and staff members shall submit training certificates to the Secretariat.

5.7.2 承辦人員將訓練證明書建檔並記錄於第一/二人體研究倫理審查委員會訓練紀錄表。

5.7.2 Staff members shall file the submitted training certificates and record them on the IRB Forms of Training Records.

5.7.3 將完成的記錄表列印，和訓練證明書影本一同存於「委員教育訓練記錄檔案夾」及「工作人員教育訓練記錄檔案夾」中。

5.7.3 The printed IRB Forms of Training Records and photocopies of training certificates shall be kept in the "portfolio of training records of IRB members" and the "portfolio of training records of staff members."

5.8 紀錄保存

相關人員應依據如下規定，妥善保存各項紀錄。

5.8 Records Retention

Relevant personnel should keep all records carefully following the guidelines below.

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編號 Document Number	紀錄名稱 Name of Document	保存地點 Retention Location	保存期限 Retention Period
1	委員教育訓練記錄檔案夾 Portfolio of training records of IRB members	IRB 辦公室 IRB Office	2 年 2 years
2	工作人員教育訓練記錄檔案夾 Portfolio of training records of staff members	IRB 辦公室 IRB Office	2 年 2 years

6.附件

無。

6. Appendix

None.