臺中榮民總醫院
Taichung Veterans General Hospital

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-2005 IRB-Regulations of Operation- 2005	文件名稱 Title	專家審查管理程序書 SOP for Review by Expert Consultants
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	4	新訂。Newly composed.	20140519
B	3	由人體試驗委員會標準作業程序 5.4 版轉換成此版本 This version was converted from "Version 5.4 of the Standard Operating Procedure of the Human Research Committee."	20141125
C	3	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.原「獨立專家」更名為「專家」：文件名稱、4.1 名詞定義、5.1 流程圖之權責及內文。 2. The original "independent expert" was changed into "expert consultant" in the title of this document, in item 4.1 Definitions, and in item 5.1 Flow Chart (in "Responsible Personnel" and in the content of the flow chart). 3.刪除原附件 6.1 獨立專家檔案。 3. Deleted the original Appendix 6.1 "Portfolio of Independent Experts."	20160318
C	3	依本院規定，於 2017 年 6 月 29 日重新審視本文件，內容無須修改。 Complied with the regulations of TCVGH, this document was re-examined on 29 June, 2017, and the content did not need to be revised.	20160318
D	3	新增 5.4.4「專家得出席大會、提出審查意見報告、參與討論，但不能投票。」 Added item 5.4.4 "Expert consultants may attend IRB board meetings to give reports on reviewers' comments and participate in discussion, but they may not vote at the meetings."	20180529
E	6	1.更新參考文件 3.1 為 2011 年。 1. Updated the year of reference 3.1 to 2011. 2.修改參考文件 3.2 為「International Conference on Harmonization of Good Clinical Practice Guidelines (ICH GCP) 2016」。 2. Revised reference 3.2 into "International Conference on Harmonization of Good Clinical Practice Guidelines (ICH GCP), 2016."	20181026

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管 制 文 件 訂 修 廢 紀 錄 表
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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 Unclassified □密件 Confidential □極機密 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
E	6	3. 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」。 3. 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.	20181026
E	6	依本院規定，於 2020 年 09 月 20 日重新審視本文件，內容無須修改。 Complied with the regulations of TCVGH, this document was re-examined on 20 September, 2020, and the content did not need to be revised.	20181026

臺中榮民總醫院 2020.11.17 參考文件

訂修廢 Composed/Revised/Deleted	審核 Reviewed	核准 Approved
	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.

臺中榮民總醫院
Taichung Veterans General Hospital

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

文件編號 Document Number	IRB-本會-工作常規-2005 IRB-Regulations of Operation- 2005	文件名稱 Title	專家審查管理程序書 SOP for Review by Expert Consultants

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.	

臺中榮民總醫院
2020.11.17
參考文件

※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

為促使本院第一/二人體研究倫理審查委員會提供專家協助計畫案審查或提供諮詢之管理有一明確之規範，特制訂本管理程序書。

1. Purpose

The purpose of this SOP is to provide specific guidelines for the management of expert consultants reviewing research protocols or giving advice.

2.適用範圍

凡本院第一/二人體研究倫理審查委員會（副）主任委員認為計畫案研究之議題非委員專業領域或存在須利益迴避的情況時，可以邀請院內或院外其他特殊專業領域之專家協助審查或提供專業的諮詢之管理均適用本管理程序書。

2. Scope

This SOP applies to the situation in which expert consultants with special expertise from within or outside TCVGH are invited to review a research protocol or provide professional advice when the IRB (Vice) Chair considers that the topic of the research protocol does not correspond to the professional disciplines of IRB members, or if there is a conflict of interest.

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 專家

為不參與該項研究的院內或院外人員，提供研究計畫公正的建議及評論。

4.1 Expert Consultant

Expert consultants are personnel from within or outside TCVGH, who are not involved in a study and can provide impartial suggestions and comments about the study protocol.

5.作業內容

5. Procedure

5.1 專家審查管理流程圖

5.1 Flow Chart of the SOP for Review by Expert Consultants

流程 Flow Chart	權責 Responsible Personnel	相關文件 Relevant Documents
接獲專家審查需求 Need of Review by Expert Consultants	承辦人員 Staff Members	
↓		
推薦與遴選 Recommendation and Selection	委員/執行秘書/(副)主任委員 IRB Members/ Executive Secretary/ (Vice) Chair	個人基本資料/三年內臨床試驗相關訓練證明書影本/簽署保密、利益衝突協議書/聘書/專家檔案 Personal Information/Copies of Training Certificates on Clinical Trials within Three Years/Signed Statements of Confidentiality and Conflict of Interest/Contracts/Files of Expert Consultants
↓		
協助計畫案審查 Reviewing Protocols	專家 Expert Consultants	研究計畫資料 Documents of Research Protocols
↓		
紀錄保存 Records Retention	承辦人員 Staff Members	

5.2 接獲專家審查需求

當（副）主任委員認為計畫案研究之議題非委員專業領域，或存在須利益迴避的情況時，可以邀請院內或院外其他特殊專業領域之專家協助審查或提供專業的諮詢。

5.2 Need of Review by Expert Consultants

If the (Vice) Chair considers that the topic of a research protocol does not match the expertise of IRB members, or if there is conflict of interest, expert consultants with relevant expertise from within or outside TCVGH may be invited to review the protocol or provide professional advice.

5.3 推薦與遴選

5.3 Recommendation and Selection

5.3.1 委員、執行秘書、副主任委員或主任委員可依需要隨時推薦專業諮詢人選。

5.3.1 IRB members, Executive Secretary, Vice Chair, or Chair may recommend candidates of expert consultants anytime based on needs.

5.3.2（副）主任委員審視專家之專長，徵詢專家意願後，請專家提供以下資料：

5.3.2 After reviewing the expertise of candidates for expert consultants and consulting with them about their willingness to serve, the (Vice) Chair shall ask them to provide the following documents:

5.3.2.1 個人基本資料。

5.3.2.1 Personal information

5.3.2.2 三年內臨床試驗相關訓練證明書影本。

5.3.2.2 Copies of training certificates on clinical trials within three years

5.3.2.3 簽署保密/利益衝突協議書。

5.3.2.3 Signed statements of confidentiality and conflict of

interest.

5.3.2.4 主任委員致送聘書，聘期五年，期滿得續聘。

5.3.2.4 The Chair shall give a five-year renewable contract to each expert consultant.

5.3.2.5 承辦人員將專家之姓名及專長建檔。

5.3.2.5 Staff members shall create a file with each expert consultant's name and expertise.

5.4 協助計畫案審查

5.4 Reviewing Protocols

5.4.1 承辦人員提供「研究計畫資料」給專家審查。

5.4.1 Staff members shall provide expert consultants with relevant documents of research protocols for them to review.

5.4.2 專家審查研究計畫後，完成審查意見表供人體研究倫理審查委員會審核。

5.4.2 Expert consultants shall fill out relevant reviewer's forms and submit them to the IRB after reviewing protocols.

5.4.3 專家所做的報告，應與其他審查委員之報告一同存檔。

5.4.3 Reports by expert consultants shall be filed along with the reports by other reviewers.

5.4.4 專家得出席大會、提出審查意見報告、參與討論，但不能投票。

5.4.4 Expert consultants may attend IRB board meetings to give reports on reviewers' comments and participate in discussion, but they may not vote at the meetings.

5.5 紀錄保存

相關人員應依據如下規定，妥善保存各項紀錄。

5.5 Records Retention

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

編號 Document Number	紀錄名稱 Name of Document	保存地點 Retention Location	保存期限 Retention Period
1	專家檔案資料 Files of Expert Consultants	IRB 辦公室 IRB Office	5 年 5 years

6.附件

無。

6. Appendix

None.