



高雄醫學大學附設中和紀念醫院

Kaohsiung Medical University Chung-Ho Memorial Hospital

文件編碼 Document code	1.6	檔案名稱 File name	科學審查及其他專家／受試者(團體)代表之諮詢 Scientific Review and other Expert Consultant/Subjects (Groups) Representative Consultant		
公告日期 Announcement date	2018年1月1日 January 1, 2018	執行日期 Implementation date	2018年1月1日 January 1, 2018	版次 Version	11版 Ver. 11

1.目的 Purpose

訂定人委會聘請獨立科學審查專家及徵詢其他專家意見時的標準流程。

To establish the standard operating procedure for invitation of independent scientific expert reviewer and consultation of expert opinions.

2.適用範圍 Scope

科學審查及其他專家之角色職責及徵詢、聘任流程。

The roles and responsibilities of scientific reviewer and other experts and the processes for invitation and employment.

3.參考文件 References

3.1 人體試驗管理辦法 (2016年4月)

Regulations on Human Trials (April 2016)

3.2 醫療器材優良臨床試驗作業規範 (2015年10月)

Regulations on Good Clinical Practices for Medical Devices (October 2015)

3.3 藥品優良臨床試驗準則 (2014年10月)

Regulations for Good Clinical Practice (October 2014)

4.名詞定義 Terminology

4.1獨立科學審查專家：能對研究計畫書提供科學審查意見或公正評論，且不參與該項研究進行的學者/專家。

Independent scientific expert reviewer: academic experts or specialist that can provide scientific review opinions or impartial comments on the research protocols and are not involved in anyway with the research.

4.2其他專家：足以維護受試者權益的特殊團體代表，如宗教、倫理、社會科學等團體之受試者代表。

Other experts: representatives of special populations that uphold the rights of



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the subjects, e.g. subject representatives from religious, ethical and social science communities.

4.3特殊案件：指易受傷害族群的受試者所參與之案件，如未成年人、受刑人、原住民、孕婦/胎兒、決定能力欠缺的成年人(身心障礙、精神病患、認知能力不足者)、生存力不明之新生兒、新生兒出生後確定不能存活、社區或特定族群、學生/員工等，或審查專家認為有疑慮之案件。

Special cases: research protocols participated by subjects from vulnerable populations, e.g. minors, inmates, indigenous people, pregnant women/fetuses, adults who do not have capacity to make decisions (mental and physical disability, mental patients, cognitively impaired individuals), newborns with unclear survival, newborns that are unviable, community or underprivileged populations, students and employees, or those cases at discretion of the reviewers.

5.作業內容 Scope of operation

5.1流程

Process

程序 Procedure	權責 Rights and responsibilities	相關文件 Related documents
評估科學審查及其他專家的聘任需求 Assess the needs for hiring scientific reviewers or other specialists	執行秘書或委員 Executive secretary or committee member	確認計劃書內支持試驗產品臨床試驗的資訊 Verify the information supporting the tested product in the clinical trial protocol
推薦候選人 Candidate recommendation	行政人員或委員 Administrative staff or committee member	提供候選人名單 Submit candidate lists
邀請專家審查	主任委員	聘任



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Invitation of experts	Committee director	Employment
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5.2職責

Responsibilities

5.2.1 執行秘書或委員：評估審查之研究案件是否需要科學審查及其他專家提供意見或建議。

Executive secretary or committee member: assess the need for the research document under review to require additional scientific reviewer or expert's opinions.

5.2.2 行政人員或委員：推薦科學審查或其他專家候選人。

Administrative staff or committee member: recommendation of candidates for scientific reviewers and other experts.

5.2.3 主任委員：聘任科學審查及其他專家/受試者(團體)代表。

Committee director: hiring of scientific reviewers, experts and subject (group) representatives

5.3細則

Principles

5.3.1 評估科學審查及其他專家的聘任需求

Assess the needs for hiring scientific reviewers or other specialists

5.3.1.1 秘書分案或委員審查研究案件時，確認計劃書內支持試驗產品臨床試驗的資訊，評估需要科學審查或其他專家或受試者(團體)代表提供諮詢意見。

When reviewing or distributing the research documents for review, the executive secretary or committee members shall verify the information in the protocols that support the product under clinical



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trial, and assess the needs for hiring additional scientific reviewers and experts or subject (group) representatives to provide professional comments.

5.3.1.2 若無一位以上科學或相關專業領域的委員能審查計畫書時，得延後入會審查，並尋求科學審查及其他專家進行審查。

If no committee members from scientific or other related professional backgrounds are available for protocol review, then the review of the submission shall be postponed; seek out other scientific reviewers or experts to conduct the protocol review.

5.3.2 推薦諮詢專家/受試者(團體)代表人選與聘任

Recommendation and employment of expert/subject representative candidates.

5.3.2.1 建立專家人才或特殊身份代表資料庫，列出科學審查及其他專家/受試者(團體)代表的姓名及其專業。

Establish a database on the expert talents or those with special status; compile a list of names and professions of the scientific reviewers, experts and subject (group) representatives.

5.3.2.2 若超出既有的名單，且審查委員無建議人選，則由工作人員詢問其他醫院是否有相關領域之委員或該專長之人員，經電話向主委或秘書確認同意，並徵詢該專家意願後推薦。

If the list exceeds the currently available lists and there are no recommended candidates from the review committee, then the staff member shall inquire other hospitals for members or experts in related fields of expertise. The staff member shall verify with the



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committee director or secretary via telephone, then make the recommendation after acquiring consent from the expert.

5.3.2.3 工作人員或委員提供科學審查及其他專家推薦名單後，由主任委員聘任。

The committee director will proceed with the hiring of candidates after the staff member or committee member have made the submission.

5.3.2.4 科學審查及其他專家/受試者(團體)代表之聘任期為兩年。

The term of service for the scientific reviewer, expert and subject (group) representative is 2 years.

5.3.2.5 聘任之科學審查專家應提供以下資料：

The scientific reviewers and experts shall provide the following information:

A.履歷。

Resume.

B.專家保密協議書。

Expert's agreement on confidentiality.

C.專家利益衝突協議書。

Expert's agreement on conflicts of interests.

5.3.2.6 受試者(團體)代表應提供以下資料：

The subject representative (group) shall provide the following information:

A.履歷。

Resume.



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B.受試者(團體)代表保密協議書。

Subject (group) representative's agreement on confidentiality.

5.3.3 科學審查及專業諮詢服務

Scientific review and professional consultation service

5.3.3.1 行政人員提供研究計畫檔案給合適的審查專家/受試者(團體)代表，依據標準作業流程 (SOP 2) 進行科學審查及專業諮詢。

The administrative staff provides research protocol files for the suitable reviewers, experts and subject (group) representatives, who will then conduct scientific review and professional consultation according to SOP 2.

5.3.3.2 審查專家/受試者(團體)代表提出完成的科學審查/諮詢報告，以供人委會參考。

Reviewer/subject (group) representatives submit the completed scientific review/consultation reports to the IRB for reference.

A.填寫初審意見表、專家諮詢意見表(附件一)或受試者(團體)代表諮詢意見表(附件二)。

Fill out the initial reviewer's comment form, expert consultation comment form (Attachment 1) or the subject (group) representative's comment form (Attachment 2).

B.工作人員將相關資料，送交與會委員，確保於會議前委員預先審閱相關資料。

Staff members provide the committee members with relevant information beforehand to ensure that members will review the information before the IRB meetings.



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5.3.3.3 科學審查及其他專家得參加人委會會議提出報告並參與討論，但無投票權或表決權。

While scientific reviewers or other experts may attend the IRB meeting and join in the discussion, they are not eligible for voting and do not have voting rights.

5.3.4 結束專家諮詢聘任

End of expert consultant employment

5.3.4.1 科學審查及其他專家/受試者(團體)代表得自行或由人委會提出終止聘任。

The scientific reviewer, expert and subject (group) representative may voluntarily submit application to end terms of employment, or via proposal by the IRB.

5.3.5 歸檔

Document Filing

5.3.5.1 科學審查專家/受試者(團體)代表之履歷、保密協議書、利益衝突協議書存放於專屬檔案中。

Store documents (e.g. resume, confidential agreement, conflict of interests agreement) from the scientific reviewers/subject (group) representatives as a separate file.

5.3.5.2 專家諮詢意見表或受試者(團體)代表諮詢意見表，存放於計畫檔案中。

Store the expert or subject (group) representatives' consultation comment forms in the protocol files.

6.附件 Attachment



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6.1 附件一 (KMUH/IRB/AF/1.6-01/11.0)專家諮詢意見表

Attachment 1 (KMUH/IRB/AF/1.6-01/11.0) Expert's Consultation Comment Form

6.2 附件二 (KMUH/IRB/AF/1.6-02/11.0)受試者(團體)代表諮詢意見表

Attachment 2 (KMUH/IRB/AF/1.6-02/11.0) Subject (Group) Representative Consultation Comment Form