



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	1.7	檔案名稱 File name	研究倫理諮詢與輔導作業 Research Ethics Consultation and Counseling		
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

提供有關研究倫理相關諮詢與輔導之處理原則。

Provides principles on consultation and counseling of research ethics.

2. 適用範圍 Scope

計畫主持人、研究人員或相關人員對委員會之作業流程、決議事項、研究計畫所涉及的倫理議題等產生疑慮，要求溝通、諮詢與輔導。

When the principal investigator, research staff or related personnel have questions regarding the operational procedures, resolutions and ethical issues involved by the studies, and are requesting communication, consultation and counseling.

3.參考文件 References

3.1 World Health Organization, Operational Guidelines for Ethics Committees that Biomedical Research, 2000.

3.2 International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP),2006.

3.3藥品優良臨床試驗準則 (2010年7月)

Regulations for Good Clinical Practice (July 2010)

4.名詞定義 Terminology：無 NA

5.作業內容 Scope of operation

5.1流程 Process

程序 Procedure	權責 Rights and responsibilities
受理諮詢與輔導要求 Accepting request for consultation and counseling	計畫主持人/行政人員 Principal Investigator/Administrative staff



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諮詢與輔導 Consultation and counseling	教育執行秘書 Educational executive secretary
主任委員裁示 Decision of the committee director	主任委員 Committee director
文件歸檔 Filing of documents	行政人員秘書 Administrative <u>staff</u> secretary

5.2 職責Responsibilities

5.3 細則Rules

5.3.1 諮詢與輔導

Consultation and counseling

5.3.1.1 計畫主持人、研究人員或相關人員填寫諮詢與輔導記錄表(附件)提出諮詢與輔導要求。

The principal investigator, research staff or related personnel fills out the consultation and counseling record form (attachment) and submits the request for consultation and counseling.

5.3.1.2 承辦人依據諮詢與輔導內容協助處理。

The staff in charge will provide assistance according to the nature of the consultation and counseling.

5.3.1.3 若屬行政作業範圍，承辦人得直接處理，並填寫諮詢與輔導之途徑與紀錄表連同相關資料呈執行秘書。

If the request is within the scope of administrative operation, the staff in charge will handle directly, and submit the method for consultation/counseling to the executive secretary, along with the record form and related information.



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5.3.1.4 若屬行政作業以外的諮詢與輔導要求（如計畫主持人認為困難進行之倫理議題或對委員會之決議表示異議者），承辦人協助填寫諮詢與輔導紀錄表連同相關資料呈給執行秘書安排諮詢與輔導。
If the request is outside of the administrative operation, (e.g. if the principal investigator feels certain ethical issue is difficult, or has objection towards decisions made by the IRB), the staff in charge will assist the applicant in completing the consultation and counseling record form, and submit to the executive secretary along with related information, who will then schedule the consultation/counseling session.

5.3.1.5 執行秘書視需要可決定是否提交主任委員裁示。

The executive secretary may determine whether to submit the request for decision making by the committee director.

5.3.1.6 主任委員裁示以下列兩種處置方式：

The committee director will make the following two decisions:

A. 提交委員會討論。

Submit for discussion during IRB meetings.

B. 派總幹事、執行秘書或承辦人進行後續追蹤或提供進一步諮詢與輔導。

Have the general director, executive secretary or staff in charge to conduct follow-up or provides further consultation/counseling.

5.3.2 文件歸檔

Filing of documents

將諮詢與輔導資料儲存於計畫專屬檔案中。



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Store the information on consultation and counseling into the specific protocol files.

6.附件 Attachment

6.1附件一 (KMUH/IRB/AF/1.7-01/11.0)諮詢與輔導之途徑與紀錄表

Attachment 1 (KMUH/IRB/AF/1.7-01/11.0) Consultation and Counseling Record Form