



# 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	3.5	檔案名稱 File name	受試者投訴及申訴案件作業 Subjects complaints and appeals casework		
生效日期 Effective 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

為令參與本會核准之人體研究的受試者或其家屬，對其權益或福祉；或相關人員對本會申請或核准之人體研究內容、過程或執行有疑慮時，提出申訴有所依據。

This document provides a foundation of appeals for subjects or their families who have doubts when participating in IRB-approved human trials regarding their right or welfare; or for relevant personnel who have doubts when applying or conducting IRB-approved human trials regarding the contents, process or implementation of the studies.

## 2.適用範圍 Scope

本標準作業程序適用於對本會申請或核准之人體研究案有疑慮者或對研究計畫相關人員或廠商等之反映意見，悉依以本標準作業流程辦理。

The SOP is applicable to all doubts on applying or conducting IRB-approved human trials, or comments on research-related personnel or sponsors. All matters shall be processed in accordance with this SOP.

## 3.參考文件 References

### 3.1 FERCAP 人體試驗委員會標準作業流程（2005年3月）

The Standard Operational Procedures for FERCAP Institutional Review Board (March 2005)

### 3.2 人體試驗管理辦法（2009年12月）

Regulations on Human Trials (December 2009)

### 3.3 人體研究法（2011年12月）

Human Subjects Research Act (December 2011)

### 3.4 人體研究倫理審查委員會組織及運作管理辦法（2012年8月）



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## The Organization and Operational Regulations for Institutional Review Board for Human Subject Research (August 2012)

### 4. 名詞定義 Terminology

4.1 投訴：研究對象(受試者)等對人體研究/試驗之執行有影響其權益、安全、福祉之虞時，向本院人體試驗審查委員會提出反應者。

Complaints: the research targets (subjects) have doubts about their rights, safety and welfare that may be affected by the implementation of the human research/trial, and thus submit their doubts to the IRB.

4.2 申訴：研究計畫相關人員(含委託廠商)等對本院人體試驗審查委員會之申請、審查、或稽核等作業相關有疑慮時，向本院人體試驗審查委員會提出反應者。

Appeals: the research-related personnel (including the sponsor) have doubts about the operations such as application, review or audition of the IRB, and thus submit their doubts to the IRB.



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## 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
受理投訴 Receive complaints	執行秘書 Executive secretary	投訴記錄表 Complaint record
調查、資料蒐集 Investigation and data collection	總幹事/執行秘書 Director general/Executive secretary	投訴記錄表 Complaint record
行政會議討論決議 Discussion and resolutions at the administrative meeting	主任委員/副主任委員/總幹事/執行秘書 Committee director/Deputy committee director/Director general/Executive secretary	投訴記錄表 Complaint record
回應 Responses	執行秘書 Executive secretary	投訴/諮詢事件行政會議決議通知 Complaint/Consultation events administrative meeting resolution notification
彙整存檔 Summary and documentation	行政秘書 Administrative secretary	投訴記錄表、投訴/諮詢事件行政會議決議通知 Complaint record, complaint/Consultation events administrative meeting resolution notification

### 5.2 職責 Responsibilities

5.2.1 召集人：主持會議討論投訴案件，並作決策。

Convener: the person to lead the meeting discussion about complaints and make decisions.



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5.2.2 主任委員：主持行政會議討論決議投訴案件之處理方式。

Committee director: leads the administrative meeting to discuss and decide the handling approaches for complaints.

5.2.3 總幹事：受理投訴案件，調查與蒐集投訴/申訴案件必要之資訊。並將行政會議之決議回覆予投訴人，並應保護投訴者的隱私。

Director general: receives complaints, investigate and collect necessary information regarding the complaints/appeals, inform the person who files the complaints about the resolutions of the administrative meeting, and protect the privacy of the person who files the complaints.

5.2.4 執行祕書：受理投訴案件，調查與蒐集投訴/申訴案件必要之資訊。並將行政會議之決議回覆予投訴人，並應保護投訴者的隱私。

Executive secretary: receives complaints, investigate and collect necessary information regarding the complaints/appeals, inform the person who files the complaints about the resolutions of the administrative meeting, and protect the privacy of the person who files the complaints.

5.2.5 行政秘書：將行政會議決議回應意見等作成紀錄、歸檔。

Administrative secretary: documents and archive the resolutions and responses from the administrative meeting.

5.2.5 執行祕書有職責與受試者等投訴者就權益或福祉問題進行溝通；必要時列入委會定期行政會議討論、決議。

Executive secretary: responsible for communicating with the person who files the complaints (e.g. subjects) about the rights or welfare issues, and schedule the issues into routine IRB administrative meetings for discussion and resolutions if necessary.



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## 5.3 細則 Rules

### 5.3.1 受理投訴

#### Receive complaints

5.3.1.1 執行秘書/總幹事受理投訴/申訴案件。主任委員、副主任委員、總幹事、執行秘書得轉介投訴/申訴案件予行政秘書。

The executive secretary/director general will receive complaints/appeals. The committee director, deputy committee director, director general and executive secretary shall refer the complaints/appeals to the administrative secretary.

5.3.1.2 投訴者應以「投訴記錄表」載明投訴事件，以書面或電子郵件寄至本會投訴信箱：irb-app@ms.kmuh.org.tw。

The person who files complaints shall describe the complaints in the “complaint record”, and send to the IRB mail through post or e-mail at irb-app@ms.kmuh.org.tw.

5.3.1.3 行政人員應將電話投訴事件記錄於「投訴記錄表」中(附件一)。

The administrative staff shall record the telephone complaints in the “complaint record” (Attachment 1).

### 5.3.2 調查、蒐集資訊

#### Investigation, information collection

5.3.2.1 執行秘書/總幹事確認投訴人並蒐集相關資料、調查。

The executive secretary/director general will verify the person who files the complaints and collect relevant data and investigation results.

5.3.3 召集人或主任委員主持行政會議討論、決議投訴/申訴案件。必要時，計畫主持人得列席說明。



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The convener or committee director will organize administrative meetings to discuss and decide complaints/appeals. The PI may need to attend the meeting for explanation if necessary.

#### 5.3.4 總幹事/執行秘書將行政會議決議「投訴事件回覆表」回覆予投訴人。

The director general/executive secretary will inform the person who files the complaints about the resolutions of the “complaint responses”.

#### 5.3.5 行政秘書進行資料存檔

The administrative secretary performs file documentation

##### 5.3.5.1 「投訴記錄表」(附件一)正本存於投訴檔案夾中。

The original file of the “Complaint Record” (Attachment 1) is stored in the folder for compliant files.

##### 5.3.5.2 「投訴記錄表」(附件一)副本存於該計畫案的檔案夾中。

The copy of the “Complaint Record” (Attachment 1) is stored in the folder of the study protocol.

##### 5.3.5.3 妥善儲存資料夾於適當標示的檔案櫃中。

The files shall be retained properly in the file closet with proper labels.

## 6.附件 Attachment

### 6.1 附件一(KMUH/IRB/AF/3.5-01/11.0) 投訴記錄表

Attachment 1 (KMUH/IRB/AF/3.5-01/11.0) Complaint Record

### 6.2 附件二(KMUH/IRB/AF/3.5-02/11.0) 投訴/諮詢事件行政會議決議通知

Attachment 2 (KMUH/IRB/AF/3.5-02/11.0) Complaint/Consultation Events Administrative Meeting Resolution Notification