1.目的 Purpose

為提供治療危急或重大病患需使用未獲衛福部許可證之藥物贈品，及未獲衛福部許可證之藥物樣品，保障接受緊急治療病患之權益，規範其申請流程及提供審查依據。

To allow treating critical patients or patients with major illnesses and require using medicinal products/medical devices that have not been approved by Ministry of Health and Welfare, and protect patient's rights to receive emergency use, it is hereby to regulate the application process and the requirements of review foundations.

2. 適用範圍 Scope

適用於已獲衛福部許可證之藥物贈品及申請進口目前未經衛福部核准上市之藥物樣品，供診治危急或重大病患之使用。

It is applicable to the applications for import medicinal products/medical devices that have not been approved by Ministry of Health and Welfare for listing to the use for treating critical patients or patients with major illnesses.

3.參考文件 References

3.1 藥物樣品贈品管理辦法 (2003 年 4 月)

Regulations Governing Medicinal Sample Gifts (April 2003)

3.2 藥品優良臨床試驗準則（2014 年 10 月）

Guidelines of Good Clinical Practice (October 2014)

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

3.4 International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

4.名詞定義 Terminology

4.1 危急或重大病患：患有危及生命或嚴重失能疾病患者。

Critical patients or patients with major illnesses: refer to the patients with life-threatening diseases or with severe disabilities.

4.2 緊急治療:目前國內無其他可比較或適宜的替代療法,但有急迫治療需求。

Emergency use: refers to the requirements for urgent treatment and not other comparable or alternative therapies are available so far in the country.

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
受理申請資料（文件齊全） Receive the application (the submission is completed)	申請人 Applicant	送審文件 Files for review
實質審查 Substantial review	審查委員/專家 Reviewers/Expert	送審文件 Files for review
會議討論/決議 Discussion/Resolution	人委會 IRB	送審文件 Files for review 審查紀錄 Review records
發送決議證明/文件歸檔 Deliver certificate of resolutions/archive files	行政秘書 Administrative staff	審查會議紀錄 Review meeting minutes

5.2 職責 Responsibilities

5.2.1 工作人員：受理申請案件，核對申請資料，並負責將審查意見彙整通知申請人/計畫主持人，文件歸檔。

Staffs: may receive applications, verify application files, be responsible for summarizing review comments and inform them to the Applicant/PI, and archive files.

5.2.2 主任委員：指定審查委員。

Committee director: can appoint reviewers.

5.2.3 審查委員/專家：應於期限內完成審查程序，並將審查意見送交人委會工作人員。

Reviewers/experts: shall complete review procedures and send back the review comments to the IRB staffs.

5.3 細則 Rules

5.3.1 醫師申請流程

Physician application process

5.3.1.1 經專科醫師診斷判定並出具書面證明符合危急或重大病患，由該醫師提出申請並須經過單位主管覆核。

For those patients who have been diagnosed of critical or major illnesses by specialists with written certificates, the physician may submit an application and the application shall be reviewed and approved by the unit chief.

5.3.1.2 送審資料包括

The submitted files shall include

A.申請表(附件一)，內容須載明藥物贈品/樣品之名稱、型號、規格、數量、病患的病況是否符合供診治危急或重大病患之用，及確認無衛福部可使用之替代品等之替代品可使用等審核要件

The Application Form (Attachment 1) shall indicate the name, mode, specifications, quantity of the medicinal product/medical device and whether it is for the use or treatment for patients with critical or major illnesses. It is also required to confirm that whether MOHW-approved for listing alternatives are unavailable.

B.治療計劃書 (附件二) 應載明：

Treatment Protocol (Attachment 2) shall specify:

(A)病患之病況、得申請供診緊急治療之理由、無法使用常規治療或療效不佳或也無適宜替代療法之判斷過程，並檢附病患醫療紀錄供審核。

Patient's disease status, the reasons for applying emergency use, the reasons for unable to receive routine treatments, poor efficacy, or no proper alternative therapies available. Patient's medical records shall also be attached for review.

(B)本次治療(包括醫療器材)之適應症、完整治療方法及療程、預期效果及副作用(包括可能發生之併發症疾處理方法)、後續追蹤計畫等內容，並檢附國內外相關文獻資料以供佐證。

The indications of the treatment (including medical devices), complete therapeutic approaches and courses, expected effects and side effects (including potential complications and corresponding handling), subsequent follow-up plans, and the attachment of national and international literature for reference.

C.病患同意書：讓病人或其法定代理人接受藥物贈品/樣品治療之權利、義務及相關資訊(附件三，AF-039/08.0)。病人或其法定代理人、配偶、親屬或關係人等相關人員須簽屬同意。

Patient Consent Form: The patient's or his/her legal representative's right and obligation to receive the treatment of medicinal products/medical devices and relevant information (Attachment 3, AF-039/08.0). The patient or his/her legal

representative, spouse, relatives or person of interest shall sign the consent form.

D. 藥物贈品/樣品原產國上市證明、仿單或各國醫藥品集收載影本：有關原產國上市證明部分，得以產製國官方出具之製造證明，及美國或歐盟會員國最高衛生單位出具之自由販賣證明替代。

Certificate of listing in the country of origin of the medicinal product/medical device, monograph or copies of compendium of pharmaceuticals in individual countries: The certificate of listing in the country of origin can be replaced with the certificate of manufacturing issued by the country of origin, and the free sale certificate issued by the highest hierarchical health department of the US and EU member states.

5.3.2 行政人員受理送審文件，確認送審相關文件完備後，需填寫「初審案簽收核對表」以確認收案。

The administrative staff will receive submitted files, verify whether the files are prepared completely and fill in an “Initial Review Verification Form” to confirm files have been well-received.

5.3.3 主任委員指定一位醫療背景委員進行科學性及倫理審查。

The committee director will appoint a member with medical background to perform scientific and ethical review.

5.3.4 審查委員/專家審查緊急治療計畫：委員審查期限為 3 個工作日，填寫審查意見：勾選 □核准 □修正後複審 。

Reviewers/experts review emergency use plans: The review period is 3

working days; the reviewers will fill in the review comments as selecting one the following items: □Approval □Secondary review after amendment.

5.3.4.1 核准：工作人員製作同意執行治療證明書

Approval: The staffs will prepare a certificate of approval for treatment implementation.

5.3.4.2 修正後複審：工作人員將委員初審審查結果彙整後，予計畫主持人修正回覆。

Secondary review after amendment: The staffs will summarize the review results and send them to the PI for amendments and responses.

5.3.5 人體試驗委員會核發同意執行治療證明後，計畫主持人自行函送中央主管機關審核，經中央主管機關核可後方可執行。

After the IRB issuing a certificate of approval for treatment implementation, the PI may self-deliver the files to the competent authorities for review. The study implementation will start after obtaining the approval from the Central competent authorities.

5.4 緊急治療之核備

The approval of emergency use for reference

5.4.1 緊急治療案於申請後最近一次審查會中追認。

The emergency use will be ratified on the latest review meeting after the application.

5.4.2 審查會於追認緊急治療案時，計畫主持人得出席說明緊急治療執行狀況並備詢。

When ratifying emergency use at the meeting, the PI is required to attend the meeting to describe the status of emergency use and answer questions.

5.4.3 審查會於追認緊急治療案時，若緊急治療已施行完畢，則緊急治療之追認可與結案合併進行。

When ratifying emergency use at the meeting, if the emergency use has completed, the ratification of emergency use can be reviewed together with the application for case close.

5.5 緊急治療之監督

Monitoring emergency use

5.5.1 緊急治療案執行期間，審查會得視受試者病情狀況及風險由主任委員/執行秘書派請委員1至3名實地訪查。

During emergency use, the committee director/executive secretary of the board may assign 1-3 reviewers for site inspections depends on the disease status and risks of the subjects.

5.5.2 實地訪查之結果，應由實地訪查之委員於審查會上報告。必要時，得請計畫主持人出席審議會並報告計畫執行狀況。

The results of site inspection shall be reported on the review meeting by the member who conducted site inspection. The PI may be asked to attend the meeting and report the status of study implementation if necessary.

5.6 緊急治療之結案

Case close for emergency use

5.6.1 計畫主持人應於緊急治療案執行期限完畢後4周內向委員會提交完整之書面結案報告。

The PI must submit a complete written final report to the IRB within 4 weeks after the completion of the emergency use.

5.6.2 結案報告依照一般審查程序。由原審查委員審查。

The review of final report will be following the procedures as regular review and reviewed by the original reviewers.

5.6.3 審查會若不通過緊急治療案之結案報告，則至少一年內不接受計畫主持人之任何新計畫案之申請；並要求計畫主持人於一年內再接受人體試驗研究相關法規及執行訓練課程至少 15 小時以上。

If the final report of the emergency use is not approved by the review meeting, any new applications of the PI will not be received for at least one year. The PI will also be asked to receive at least 15 hours of human study-related laws/provisions and implantation training within 1 year.

5.7 歸檔 Archiving

5.7.1 計劃案原始資料、審查意見表、同意證明書應歸檔管理。

The original data of the study, review comments and certificate of approval shall be archived.

5.7.2 工作人員將資料放置指定位置存放。

The staffs will store the files at designated locations.

6.附件 Attachment

6.1 附件一 (KMUH/IRB/AF/2.12-01/11.0)緊急治療之審查申請表

Attachment 1 (KMUH/IRB/AF/2.12-01/11.0) Review Application Form for Emergency Use

6.2 附件二 (KMUH/IRB/AF/2.12-02/11.0)治療計畫書

Attachment 2 (KMUH/IRB/AF/2.12-02/11.0) Treatment Protocol

6.3 附件三 (KMUH/IRB/AF/2.12-03/11.0)緊急治療藥品/醫療器材樣品病患同意書

Attachment 3 (KMUH/IRB/AF/2.12-03/11.0) Patient Consent Form for Emergency Medical Product/Medical Device

6.4 附件四 (KMUH/IRB/AF/2.12-04/11.0)審查意見表

Attachment 4 (KMUH/IRB/AF/2.12-04/11.0) Review Comment Form