1.目的 Purpose

此標準作業程序規範之目的為本會所使用的名詞、縮寫及標題等定義提供指引，藉以促使利用及了解本會的標準作業程序和活動。

The purpose of this standard operating protocol is to provide guidance on the terminology, abbreviations and titles used by the institutional review board (IRB), in order to promote the understanding and utilization of the standard operating procedures and activities of the IRB.

相關的定義分為兩部分：

The definitions are divided into two parts:

－本委員會相關人員個別執掌之定義。

Definition of the individual titles and roles of the personnel in the IRB.

－本委員會標準作業程序中專有名詞及縮寫的描述和定義。

Description and definition of the specific terminology and abbreviations of the standard operating procedures of the IRB.

2. 適用範圍 Scope

此標準作業程序適用於所有本會(包含高雄醫學大學暨附設中和紀念醫院人體試驗委員會第一人體試驗委員會委員、高雄醫學大學暨附設中和紀念醫院第二人體試驗委員會委員)以及相關工作人員。

This standard operating procedure is applicable to all personnel of the IRB (including Institutional Review Board I and II of the Kaohsiung Medical University Chung-Ho Memorial Hospital) and related staff members.

3.參考文件 References

3.1 赫爾辛基宣言(Declaration of Helsinki) 2013年中文版，2013

Declaration of Helsinki, 2013 Chinese Version, 2013

3.2 人體研究倫理審查委員會組織及運作管理辦法(2012年8月)

Regulations Governing the Organization and Operational Management of the Institutional Review Board for Human Subject Research (August 2012)

3.3 藥品臨床試驗計畫書主要審核事項(2014年2月)

Main review items for Drug Clinical Trial Protocol (February 2014)

3.4 藥品優良臨床試驗準則(2014年10月)

Regulations for Good Clinical Practice (October 2014)

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

3.6 倫理審查委員會得簡易程序審查之人體研究案件範圍(2012年7月)

Scope of Expedited Review of Human Clinical Trials by the Research Ethics Committee (July 2012)

3.7 醫療法(2014年8月)

Medical Care Act (August 2014)

3.8 人體試驗管理辦法(2016年4月)

Regulations on Human Trials (April 2016)

3.10 人體研究法(2011年2月)

Human Subjects Research Act (February 2011)

3.11 得免取得研究對象同意之人體研究案件範圍(2012年7月)

Scope of Human Clinical Trials Exempted from Informed Consents of Subjects (July 2012)

3.12 得免倫理審查委員會審查之人體研究案件範圍(2012年7月)

Scope of Human Clinical Trials Exempted from Review by the Research Ethics Committees (July 2012)

4.名詞定義 Terminology

以下定義來自 FERCAP (Forum for Ethical Review Committees in Asian and Western Pacific Region)、2000 年世界衛生組織、倫理委員會有關生理醫學研究的操作規範、臺灣藥品優良臨床試驗準則(Taiwan Good Clinical Practice)、人體研究倫理審查委員會組織及運作管理辦法

The definitions of the terminology are sourced from FERCAP (Forum for Ethical Review Committees in Asian and Western Pacific Region), operating procedures on physiological and medical research from the World Health Organization in 2000 and the research Ethic Committees, Taiwan Good Clinical Practice, and Regulations Governing the Organization and Operational Management of the Institutional Review Board for Human Subject Research.

5.作業內容 Scope of operation

5.1 流程

Process

程序 Procedure	權責 Rights and responsibilities
個別執掌的描述 (Description of individual titles and roles)	標準作業程序小組 Standard Operating Procedure Group
新增/修正名詞 (Addition / Amendment of terms)	標準作業程序小組 Standard Operating Procedure Group

標準作業程序中的相關名詞 Terminology of the Standard Operating Procedure	標準作業程序小組 Standard Operating Procedure Group

5.2 個別執掌的描述

Description of individual titles and roles

5.2.1 人體試驗委員會 (Institutional Review Boards, IRB)：本會共二個委員會，本會設有總召集人1位及二個委員會之主任委員、副主任委員、執行祕書。各委員會至少置15名委員，且至少2/5為院外人員與單一性別不低於三分之一。

審查範圍包含如下：

There are two Institutional Review Boards (IRB), each has one chairperson and the committee directors, deputy committee directors, executive secretaries, and at least 15 committee members for each of the review board. At least 2/5 of the members must be external specialist, and no less than 1/3 are of a single-gender.

The scope of review is as follow:

A. 臨床試驗：依藥物優良臨床試驗準則第3條定義臨床試驗係指以發現或證明藥品在臨床、藥理或其他藥學上之作用為目的，而於人體執行之研究。

Clinical trials: according to the definition of Article 3 of the Regulations for Good Clinical Practice, any investigation in human subjects intended to discover or verify the clinical, pharmacological or other pharmaceutical effects of an investigational product(s).

B. 人體試驗：依醫療法第8條定義人體試驗係指醫療機構依醫學理論於人體施行新醫療技術、新藥品、新醫療器材及學名藥生體可用率、生體相等性之試驗研究。

Human trials: according to Article 8 of the Medical Care Act, the term refers to experimental research of new medical technology, new medicament, new medical device, or the bioavailability and bioequivalence of generic drugs conducted by medical care institutions on humans based on medical theory.

C. 人體研究：指從事取得、調查、分析、運用人體檢體或個人之生物行為、生理、心理、遺傳、醫學等有關資訊之研究。

Human research: studies that are aimed to obtain, investigate, analyze or utilize information on human specimen, personal biological behaviors, physiology, psychology, genetic and medicine.

D. 人體檢體：指人體(包括胎兒及屍體)之細胞、組織、器官、體液或其衍生物質（含遺傳物質），包括剩餘檢體。

Human specimen: materials of human origin, including cells, tissues, organs, body fluids and other derivatives (including genetic material) from the human body (fetus and corpse included), and residual specimen.

E. 試驗藥品：臨床試驗中用來試驗之藥品，或當做參考之活性成分製劑或安慰劑。包括已上市藥品使用於其核准內容不同之用途、配方、包裝、適應症。

Trial drugs: medication tested in clinical trials, or active ingredient

compounds or placebos for reference, approved medications for use in different purposes, formulations, packaging and indications.

5.2.2 標準作業程序小組(以下簡稱SOP小組)

由主任委員從本會委員中挑選，負責本會標準作業程序的準備、審查及定期修訂，本會標準作業程序一致適用二個委員會。人委會委員及工作人員提出新增名詞，或對本標準作業程序所定義的任何名詞提出改正建議。

Standard operating procedure group (hereafter refer to as the "SOP group") Selected by the committee director from the IRB committee members and are responsible for preparing, reviewing and regularly revising the SOPs of the IRB. The SOPs are applicable for both IRBS; committee members and staff members either propose new terms or provide recommendation on revisions of existing terms defined by this SOP.

5.3 新增/修正名詞 (Addition /Amendment of terms)

Addition /Amendment of terms

名詞之新增與修訂，則以SOP小組針對標準作業程序之撰寫審查、頒佈與修訂進行。

The addition and amendment of terms are written, reviewed, announced and amended by the SOP group according to this SOP.

5.4 標準作業程序中的相關名詞

Terminology of the Standard Operating Procedure

5.4.1 人體研究參與者/受試者：接受研究人員進行研究的個人,研究 內容包括對該個人進行調查、分析、檢驗、治療或其他介入性 措施或互動,

從中獲取數據或可辨識之個人資料。

Human trial participant/subject: person who participate in studies by researchers, which may include investigation, analysis, test and treatment for the subject, or other intervention measures or interaction and acquirement of data and identifiable personal information.

5.4.2 試驗/研究主持人：負責執行及協調試驗/研究計畫的人。藥品臨床試驗之主持人，須符合衛生福利部執行國內藥品臨床試驗主持人資格條件（衛生署衛署藥字第0960313760號）。人體試驗之主持人，須符合衛生福利部公告之人體試驗管理辦法所定義之主持人資格條件。

Trial/Investigator: person responsible for implementing and coordinating the research/study protocol. The investigator of the Drug Clinical Trial must fulfill the qualification standards for domestic Drug Clinical Trial (MOHW Wei-Shu-Yao-Zi No. 0960313760) as announced by the MOHW; investigator of the human trial must fulfill the qualification standards defined in the Regulations on Human Trials as announced by the MOHW.

5.4.3 利益衝突 (Conflict of Interest；COI)

Conflict of Interest (COI)

指在一組狀況下，次要利益導引專業判斷或行動會對主要利益造成不當影響而產生風險。例如計畫主持人、研究人員、委員有個人的利益，充分顯示將影響其研究執行或研究審查的客觀公正性，導致產生對受試者權益或安全不當之影響。

Refers to circumstances where secondary interests may affect expert judgment and actions that could adversely affect the main interest of the

study, creating risks. For example, personal interests held by the principal investigator, research personnel or committee members that are shown to be sufficiently affecting the objectivity and fairness of the study progression or review, resulting in adverse effects on the rights and safety of the subjects.

5.4.4 財務利益衝突 (Financial Conflict of Interest；FCOI)：財務利益直接且有意義地影響研究之設計、執行、報告，或對機構應盡的義務和責任。上述財務利益包括但不限於：

Financial Conflict of Interest (FCOI): refers to financial interests that directly and significantly affect the study design, implementation, report, or due responsibilities and duties to the institution. The aforementioned financial interests include but not limit to:

A.與試驗委託者/廠商有聘僱關係。

Employment relationship with the study sponsor or vendor.

B.為試驗委託者/廠商之主管或負責人。

Executive manager or person in charge for the study sponsor/vendor.

C.為試驗委託者/廠商長期支薪之顧問。

Long-term paid consultant for the study sponsor/vendor.

D.試驗委託者所提供之年薪、產品或服務。

Salaries, products or services provided by the study sponsor.

E.擁有計畫贊助公司或其產品之私有股息(如公司股票)。

Owner of private dividends from the study sponsor or its products (e.g. company stock).

F.獲得的股息(包括股票或其相等值)，或計畫案的經費贊助金額。

Received dividend (including stock or equivalent in value) or the protocol sponsorship budget.

G.獲得與研究有關的藥品/產品/技術之所有權(包括：專利、商標、商業、版權)

Received ownership of the study medication/product/technology (including patents, trademarks, business or copyrights).

H.收取或預期收到補助款，足以影響研究的結果。

Receive or expect to receive subsidies that may significantly affect the results of the study.

5.4.5 顯著財務利益：指下列情形之一

Significant financial interests: any one of the following

A.試驗委託者所提供之年薪、產品及服務，共超過新台幣 15 萬元。

The total value of the salary, products and services provided by the study sponsor is equal to or exceeds NT$150,000.

B.獲得的股息(包括股票或其相等值)共超過新台幣 15 萬元，或 5%計畫案的經費贊助金額。

The value of the received dividend (including stock or equivalent value) is equal to or exceeds NT$150,000, or 5% of the protocol sponsorship budget.

5.4.6 非財務利益衝突 (Non-Financial Conflict of Interest；NFCOI)：指下列情形之一

Non-Financial Conflict of Interest (NFCOI): any one of the following

A.IRB 審查委員為受審研究計畫或其子計畫之主持人、共同主持人、協同主持人或委託人。

The IRB review committee member is the investigator, sub-investigator, co-investigator or sponsor of the study protocol under review or its sub-studies.

B.IRB 審查委員與受審研究計畫主持人有配偶、四親等內之血親或三親等內之姻親或曾有此關係。

The IRB review committee member is the spouse, fourth-degree blood relative, or third-degree marriage relative of the principal investigator under review.

5.4.7 行政文件 ：標準作業程序記述之各種文件，包括本會會議紀錄及投票紀錄以及標準作業程序

Administrative documents: the various documents listed in the SOP, including the IRB meeting minutes, voting records and SOPs.

5.4.8 執行中的研究檔案 ：經本會核准且仍在進行中之研究檔案，包含已被核准的文件、溝通的紀錄及報告。

Study files under progress: study files that have been approved by the IRB and are currently undergoing trial process, which include documents that have been approved, communication records and reports.

5.4.9 非執行中試驗/研究檔案：已結案之試驗/研究計畫檔案稱之，其中可包含（計畫書、計畫書變更版本、受試者同意書、宣傳資料、計畫主持人及試驗/研究地點資訊、進度報告、試驗/研究中新藥安全報告、受試者受傷報告、科學性評估等）。非執行中試驗/研究檔案在試驗/研究完

成後至少須保存三年，在需要時可以取出參考。所有有關財務利益/非財務關係的申報資料以及利益衝突審查決議的文件俟試驗/研究計畫結束後保存15年。

Trial/study files not currently in progress: refers to any trial or study protocol file that has been completed, which includes (protocol, protocol amendment, informed consent form, promotional material, information on the principal investigator and trial/study location, progress report, safety report for novel drug under trial/study, subject injury report and scientific assessment). Trial/study files not currently in progress must be kept for a minimum of 3 years after the trial/study has been completed, and be made available when requested. All declaration on financial interests/non-financial interests and resolution documents on COI reviews must be kept for a minimum of 15 years after the study/research has been completed.

5.4.10 簡易審查：經本會執行秘書判定送審案件為符合簡易審查案件後，得指派委員進行簡易審查，其審查結果需呈各該委員會。

Expedited review: study protocols deemed suitable for expedited review by the executive secretary of the IRB will be assigned to committee members for expedited review. The results of the review will need to be signed off by each of the IRB.

5.4.11 主檔/原始檔案文件：將標準作業程序、指引、說明（含制定者、審查者及獲授權人員真實簽署的手冊等文件的原始版本），有系統地貯藏在有安全設施及管制的櫃子。

Maser file/original file document: systematical storage of the SOP, guidelines and description (including the original version of the documents authentically signed by the document writers, reviewers and authorized personnel) in a cabinet with access and safety control.

5.4.12 會議紀錄：指由適當組成（有法定人數出席）的本會會議的正式紀錄，其中記載了議程所列的事件、活動及行動。會議紀錄完整地標示出每一項計畫書及（或）活動，並記錄各項表決的結果。本會會對送交一般、基因、易受傷害計畫案審查的每份計畫分別表決。表決採不記名投票方式，紀錄應註明各項決定的票數。

Meeting minute: refers to the official record of the IRB meetings as attended by appropriate parties (quorum attendance). The record should contain the events, activities and actions of the meeting agenda, and completely indicate the protocols and (or) activities and results of each of the voting processes. The IRB will vote individually on each of the submitted general, genetic and vulnerable population study protocol. Voting is conducted anonymously, and the minute will contain the number of votes for each decision made.

5.4.13 緊急會議：除了例行舉行的 IRB 會議外，依實際情況需要而緊急召開之會議。出席及投票委員人數均需達法定人數方得以召開。緊急會議得以視訊方式進行。

Emergency meeting: meetings that are convened in emergency when necessary and outside of the regularly held IRB meeting sessions. The meeting is only convened when the legal quorum of committee member

attendance and voting members have been reached. The emergency meeting can be held via teleconferencing.

5.4.14 法定人數 ：本會召開會議均須與會者作出決定。本會各委員會召開審查會議應有半數以上之委員出席，其中至少1人為機構外之非具生物醫學科學背景委員，且須在會議進行討論和表決時全程在場。出席委員均為單一性別時，不得進行會議。

Quorum (minimum required number of committee members for meeting to proceed): members attending all meetings of the IRB are required to make decisions. Review meetings convened by the IRB should be attended by half or more of the committee members; at least one member should be from outside of the institution and not of medical or biological background, and must attend the meeting entirely during discussion and voting. Meeting cannot proceed if all attending members are of the same gender.

需符合下列條件始可召開會議：

The following criteria must be fulfilled before a meeting is convened:

A. 至少1人為醫療/科學委員。

At least one committee member of medical/scientific background.

B. 若本次會議討論之案件包含TFDA或國際衛生機關（如：FDA）監管之案件，至少1人需為具醫師執照之委員

If the cases to be discussed in the meeting are under supervision by the TFDA or international health agencies (e.g. FDA), then at least one committee member must have a physician’s license.

C. 至少1人為非醫療/非科學委員（具法律背景或其他公正人士）。

At least one committee member of non-medical/scientific background (legal background or a person of impartial status).

D. 至少1人為機構外委員，並且與現有之委員無親屬關係。

At least one committee member outside of the institution, and is not related to any of the current members.

E. 至少 1 人代表一般受試者的立場。

At least one committee member that represents the position of the subject.

5.4.15 弱勢團體**(**Vulnerable subjects) ：可能會因為受參與試驗/研究之預期利益(Undue influence)，或拒絕參加可能會遭階級制度中資深人員報復之不當影響而被迫自願參加(Coercion)試驗/研究的受試者。例如：學生、附屬醫院與實驗室人員、製藥界的員工、軍人、遭拘留的犯人。其他易受傷害的受試(訪、檢)者包括絕症患者、安置在護理之家的人、失業或貧窮人家、發生危急情況的人、弱勢人種、無家可歸者、遊牧民族、難民、少數民族與自己無法給予同意的人。

Vulnerable subjects: subjects who may receive undue influence from participating in the trial/study, or those who have refused to participate in the trial/study, but were forced to participate under coercion and threat of retribution by senior personnel within the hierarchy system. Examples are: students, hospital and laboratory personnel, pharmaceutical employees, military personnel and prisoners. Other vulnerable subjects (interviewee or trial) may include terminally ill patients, residents of care facilities, unemployed or impoverished households, people experiencing

emergencies, disadvantaged populations, homeless people, nomadic tribes, refugees, minorities and people who could not give consent.

5.4.16 醫療器材： 醫療器材係指任何非經由化學作用或被代謝來達成其任何意圖目的之健康照護產品。醫療器材包括的項目如診斷性檢驗套件、枴杖、電極、特殊病床、心臟整律器、動脈移植物、眼球內水晶體及骨科矯形針等。醫療器材也包括診斷輔助物品，如用作體外診斷疾病及其他情況（如懷孕）的試劑及檢驗套件

Medical device: refers to any healthcare product that achieves its intended purposes without any chemical reactions or metabolism by the body. Examples of medical device include diagnostic test kits, crutches, electrodes, specialized beds, cardio pacemakers, arterial implants, artificial lens and orthopedic pins. Medical device also includes diagnostic aides like the reagents and test kits for *in vitro* disease diagnosis and other circumstances (e.g. pregnancy test).

5.4.17 諮詢專家：不隸屬計畫執行單位或參與該研究，並提供研究計畫 書公正的建議及評論者。

Consulting expert: individuals who are not part of the study implementation party and do not participate in the study, and provide impartial recommendations and comments of the study protocol.

5.4.18 受試者(團體)代表：足以代表及維護受試者權益者。

Subject (group) representative: individuals who represent and uphold the rights of the subjects.

5.4.19 特殊案件：包含易受傷害族群(如未成年人、受刑人、原住民、孕婦、

身心障礙、精神病患...等)、決定能力欠缺的受試者參與之案件、或有疑慮之案件。

Special cases: studies that include vulnerable subjects (e.g. minors, inmates, indigenous people, pregnant women, mental and physical disability, and psychiatric patients, etc.) or subjects that cannot make decisions themselves, or studies that are questionable.

5.4.20 易受傷害族群：包括孩童、囚犯、孕婦、身心障礙、難民、經濟能力較差、教育程度較低等，容易遭受強迫及不當影響者。

Vulnerable population: includes children, inmates, pregnant women, mental and physical disability, refugees, financially disadvantaged, low education level, and those that are easily coerced or forced.

5.4.21 最小風險：對身體或心理上造成的傷害的機會或程度，相當於健康受試者的日常生活、常規醫學及心理學檢查所造成者，並沒有因為參與試驗而增加。

Minimal risk: the chances or degrees of mental or physical injuries that are equivalent to what a healthy subject receives during normal daily life, routine medical and psychological examinations, and have not been increased by participation in the clinical study.

5.4.22 第一類風險：相當於最小風險

Type 1 risk: equivalent to minimal risk.

5.4.23 第二類風險：超過最小風險，但對受試者有直接利益。

Type 2 risk: above minimal risk, but directly benefits the subject.

5.4.24 第三類風險：超過最小風險，但對受試者無直接利益，但有助於了解

受試者之情況。

Type 3 risk: exceeds minimum risk, has no direct benefit to the subject, but can help to delineate information about the subject.

5.4.25 第四類風險：超過最小風險，且對受試者無直接利益，但研究主題可得到價值的結果。

Type 4 risk: exceeds minimum risk, has no direct benefit to the subject, but the research can potentially yield valuable results.

5.4.26 第一期臨床試驗(phase I)：以了解藥物毒性為目的之安全性研究，對象為健康志願者。指研發階段新藥用於人體試驗，測試人體藥物代謝或藥物動力作用，或研究劑量增加所導致的副作用。

Phase I clinical trial: A safety study designed to investigate the toxicity of the trial substance, usually targeted toward healthy volunteers. Example of phase I trials include research on novel drugs for use in humans, study on the metabolism or pharmacokinetic of human drugs, or study of the side effects from increasing study dosage.

5.4.27 第二期臨床試驗(phase II)：以了解藥物療效為目的之初步療效觀察，對象為病人。人體試驗藥物代謝、結構活動力的關聯或動力機制或應用研發新藥來探究生物現象或疾病進程。

Phase II clinical trial: Observation on the initial therapeutic efficacy of substances, usually targeted toward patients. Types of phase II studies include study on drug metabolism in humans, relationship between stricter and activity, pharmacokinetic, or investigation of biological phenomenon and disease progression using novel drugs in research.

5.4.28 第三期臨床試驗(phase III)：以確認療效及安全性為目的之完整療 效評估，對象為病人及對照組。Phase IIIa 尚未通過主管機關審核。Phase IIIb 已通過主管機關審核。採「實驗組─對照組」方式 驗證藥效，以獲取更多用藥安全的資訊，供醫師臨床使用參考。

Phase III clinical trial: Complete assessment of the therapeutic efficacy and safety of the substance, usually targeted toward patients and control groups. Phase IIIa: study not yet approved by competent authority agency; Phase IIIb: study approved by competent authority agency. The efficacy of the drug is a controlled study "Control group ─ Sample group", the purpose is to obtain information on drug safety and for clinical reference by physicians.

5.4.29 第四期臨床試驗(phase IV)：藥物上市後的安全性監視，對藥物是否產生不良反應，進行長期的追蹤

Phase IV clinical trial: safety monitoring of drugs approved for marketing, and long-term follow-up on adverse drug reactions.

5.4.30 安全性監測計畫(Data and Safety Monitoring Plan)：資料及安全監測計畫是一種程序，主要在確保受試者保護之充足及適當性，內 容包括試驗主持人如何監督受試者的安全與福祉，描述嚴重不良事件、未預期事件如何處理及通報，計畫監測的廣度及頻率應根據可預期之試驗風險、複雜度及研究計畫大小訂定。

Data and Safety Monitoring Plan: a procedure that ensures the subjects are sufficiently protected and the content of the clinical trial is reasonable. The plan describes the measures investigators take to safeguard the safety

and welfare of the subjects, handling and reporting of unforeseen events and severe adverse events. The scope and frequency of the protocol surveillance should be implemented based on the expected trial risks, complexity and scale of the trial.

5.4.31 獨立數據監測委員會 (Independent Data Monitoring Committee; IDMC) (Data and Safety Monitoring Board; DSMB)：至少有3位獨立的專家組成之委員會，包含醫師、統計專家及生命倫理專家。通常為試驗委託者所設立，用來定期評估試驗進度、安全性數據與重要的療效指標，並建議試驗委託者是否繼續、修正或停止試驗。

Independent Data Monitoring Committee (IDMC) and Data and Safety Monitoring Board (DSMB): should be comprised of at least three independent experts, including physicians, statistical analysts and bioethics. This committee is usually established by the trial sponsor to regularly evaluate the trial progress, safety data and important therapeutic indicators, and to provide recommendations for the sponsor on whether to continue, revise or terminate the trial.

5.4.32 計畫案修正：通過證明函核發後，研究計畫任何修改須經本會核准。

Protocol amendment: after the letter of approval has been issued, any amendment made to the study protocol must be approved by the IRB.

5.4.33 追蹤審查：任何人體相關的研究計畫案之追蹤審查事宜,包含 期中報告、嚴重不良事件或實地訪視監測。

Follow-up review: follow-up tracking on any part of human clinical trial

protocol, including interim report, serious adverse events or site visit and monitoring.

5.4.34 變更案：在試驗進行中研究者決定修改計畫案，變更事宜包括已獲 IRB 核准但隨後需變更之部分及其他相關檔案。

Alteration: any part of the study or files that the investigator has decided to change during the study progress, which involves files or information that have been approved by the IRB but needed to be altered afterward.

5.4.35 結案報告：當計畫結束時，計畫主持人應繳交完整之結案報告給本會。

Summary report: when a study is completed, the principal investigator should submit a complete summary report of the study to the IRB.

5.4.36 撤案：新申請之研究計畫案尚未核准前，申請者/計畫主持人欲撤回該研究計畫，即可提出撤案申請。

Case withdrawal: applicant/principal investigator can submit application to withdraw any new study protocols before they are reviewed or approved.

5.4.37 不良事件(Adverse Event, AE)：受試者參加試驗後所發生之任何不良情況。此項不良情況與試驗藥品間不一定有因果關係。

Adverse Event (AE): adverse situations that occurred in subjects participating in the study, which is not always related to the trial medication.

5.4.38 藥品不良反應(Adverse Drug Reaction, ADR)：一般用於預防、診斷、治療疾病或調節生理功能的劑量下，藥品產生任何有害且非期望的反應。此項反應與試驗藥品間有合理之因果關係。

Adverse Drug Reaction (ADR): any hazardous and unexpected reactions caused by medication under dosages that are generally used to prevent, diagnose, treat diseases or regulate physiological functions. This type of reaction is often causally related to the trial medication.

5.4.39 嚴重不良事件(Serious Adverse Event, SAE)：因試驗致發生下列反應者，如：

Serious Adverse Event (SAE): reactions occurred directly from the clinical trial, for example:

A.死亡：如病患死亡被認為係不良事件之直接結果。

Death: if the cause of death of the subject is the direct result of adverse event.

B.危及生命：如病患於發生不良事件時有死亡危險，或如繼續使用試驗產品可能造成病患死亡。(例如：心臟節律器功能喪失、胃腸道出血、骨髓功能抑制、輸液幫浦功能異常造成藥物劑量過量等。)

Life-threatening: patients are in danger of death by adverse events or through continuous usage of the trial medication. (For example: the loss of cardio pacemaker functions, gastrointestinal bleeding, inhibition of bone-marrow functions, drug overdose caused by abnormal infusion pump functions.)

C.導致病人住院或延長病人住院時間：如因不良事件發生導致病患需住院或延長住院時間。(例如：過敏性反應；偽膜性結腸炎；出血導致住院或延長住院時間等。)

Induced or prolonged hospitalization: a SAE that results in the

hospitalization or prolonged hospitalization of the subject. (For example: hospitalization and prolonged stay caused by allergic reactions, pseudomembranous colitis and bleeding.)

D.永久性殘疾：如不良事件對病患身體功能/結構、身體活動或生命品質，造成嚴重性、永久性的改變、損害或傷害。(例如：因藥物引起過度凝集之腦血管意外、中毒、周邊神經病變等。)

Permanent disability: permanent and severe change, damage and injury to the patient's physiological functions, body structure, activities and quality of life as caused by the serious adverse event. (For example: blood coagulation in the brain, toxicity or peripheral neuropathy caused by trial medication.)

E.導致胎兒先天性畸形：如於懷孕前或懷孕期間暴露於藥品導致胎嬰兒不良結果。(例如：母親懷孕時服用 diethylstilbestrol 造成女性胎兒罹患子宮頸癌、thalidomide 造成胎兒畸形等。)

Congenital malformation in fetuses: serious adverse fetal conditions caused by exposure to medication before or during pregnancy. (For example: up-taking diethylstilbestrol by pregnant mothers result in cervical cancer in female fetuses, and fetal deformity caused by thalidomide.)

F.其他可能導致永久性傷害需作處置者：懷疑因使用藥品造成需要內科或外科介入治療以防止病患永久性失能或傷害。(例如：Acetaminophen 劑量過量導致肝毒性，需以 acetylcysteine 治療以避免永久傷害；放射線設備造成之灼傷，需以藥物治 療；螺絲破損需更換以避免長骨

骨折之接合不良等。)

Disposal of other potentially permanent injuries: medical intervention from internal medicine or surgery required to prevent patients from suffering permanent disability or injury through usage of trial medication. (For example: liver toxicity from overdose of acetaminophen is treated by acetylcysteine to prevent permanent damage; medical treatment of burn injury by radiotherapy equipment; replacement of damaged screws to prevent imperfect bonding in bone fractures.)

5.4.40 疑似非預期嚴重不良反應 (Suspected Unexpected Serious Adverse Reaction, SUSAR)：指與試驗相關之非預期嚴重藥品不良反應。

Suspected Unexpected Serious Adverse Reaction (SUSAR): any unforeseen and serious adverse drug reactions related to the clinical trial.

5.4.41 實地訪視：IRB或其代表們所執行的行動，現場訪視研究單位，評估計畫主持人及機構執行情況，如何照顧研究對象、記錄資料 及通報發現，尤其是研究期間所發生的嚴重不良反應事件。

Site visit: the act taken by the IRB and its representatives to visit the research unit in person, assessing how the principal investigators and the study institution take care of the research subjects, record data and report findings, especially of SAEs that occurred during the study period.

5.4.42 試驗偏差：意指在不注意的情形下，導致不遵照審查通過之計畫書執行研究。

Study deviation: unintentional implementation of the study without following the approved study protocol.

5.4.43 試驗違規：意指在蓄意的情形下，導致不遵照審查通過之計畫書執行研究。

Study violation: intentional implementation of the study without following the approved study protocol.

5.4.44 追認：同意經聯合人體試驗委員會(JIRB)、國家衛生研究院倫理委員會(NHRI-IRB)、衛生福利部人體試驗委員會主審中心(C-IRB)及簽訂「臨床試驗聯盟聯合倫理審查機制議定書」，或醫院「合作意向書」之人體試驗委員會審查之計劃，其審查包括科 學審查及倫理審查。

Ratification: approval of study protocols reviewed by JIRB, NHRI-IRB, C-IRB of MOHW, and IRBs that have signed the “NRPB-IRB accords” or “Letters of intent” with hospitals. The review includes scientific and ethical components.

5.4.45 免除知情同意：不用告知受試者研究相關資訊也不用簽署同意書。

Exemption of informed consent: subjects are not informed of the study protocol details and do not sign the informed consent form.

5.4.46 改變知情同意：需告知受試族群研究相關資訊但不用簽署同意書。

Alteration of informed consent: subjects are informed of the study details but do not sign the informed consent form.

5.4.47 易受傷害族群：包括孩童、囚犯、孕婦、身心障礙、難民、經濟能力較差、教育程度較低等，容易遭受強迫及不當影響者。

Vulnerable population: includes children, inmates, pregnant women, mental and physical disability, refugees, financially disadvantaged, low education level, and those that are easily coerced or forced.

5.4.48 受刑人：受刑人是指被拘留在拘留所、監獄或懲處機構的人，或已被宣判或等待提訊、審判或判決而被拘留的人。包括法院授命在醫院或勒戒機構治療者。此定義適用於未成年人及成年人。

Inmate: persons who are incarcerated in penitentiary, prisons or correctional facilities, or those who have been detained and awaiting hearing, trial and sentencing, including those ordered by the court to undergo treatment in hospitals or rehabilitation institutions. This definition is applicable to both minors and adults.

5.4.49 已婚之未成年人(Emancipated Minor)：有行為能力者。

Emancipated Minor: minors that are engaged in marriage and are capable of making decisions for themselves.

5.4.50 成人(Adult)：達到法定年齡(年滿 20 歲)的人。

Adult: a person that has reached the legal age (20 years old).

5.4.51 未成年人(Minor)：未滿法定成年年齡(20 歲)人，當中包括嬰兒、兒童，及少年。

Minor: a person that has not yet reach the legal age (20 years old), which includes infants, children and minors.

5.4.52 無行為能力者：未滿七歲之未成年人或受監護宣告之人。

Incapable person: a minor below the age of 7 or a person under guardianship.

5.4.53 有限制行為能力者：滿七歲以上之未成年人。

Person of limited capacity: a minor above the age of 7.

5.4.54 法定代理人(Legally Authorized Representative)：代理行使無行為能

力、限制行為能力之權利義務之人。

Legally Authorized Representative: a person who is charged with exercising the rights and responsibilities of those who are incapable or have limited capacity.

5.4.55 法定監護人：父母均不能行使、負擔對於未成年子女之權利義務，或父母死亡而無遺囑指定監護人時。

Legal guardian: a person in charge of making decision when parents are incapable of exercising or bearing the rights and responsibilities of their minor children, or when the parents are deceased and there are no designated guardians for the will.

5.4.56 決定能力欠缺者：如未成年人、法律宣告受監護及輔助之人、因疾病喪失決定能力之成人或無法完整表達自主意願者。

Incapacitated person: for example, a minor, a person under legally proclaimed guardianship and assistance, an adult whose ability to make decisions is impaired by diseases, or a person who is incapable of sufficiently expressing his/her own wills.

5.4.57 受監護宣告之人：對於因精神障礙或其他心智缺陷，致不能為意思表示或受意思表示，或不能辨識其意思表示之效果者，法院得因本人、配偶、四親等內之親屬、最近一年有同居事實之其他親屬、檢察官、主管機關或社會福利機構之聲請，為監護之宣告。

Person designated for legal guardianship: The person who is incapable of expressing his/herself due to mental and cognitive impairments, or who could not discern the consequence of his/her expressed decisions. The

court of law shall proclaim the person to be placed under guardianship as requested by the person's relatives, spouse or relatives closest to the fourth degree, other relatives who are currently or have co-habitated with the person within the latest one year, prosecutors, competent authority agencies or social welfare institutions.

5.4.58 受輔助宣告之人：對於因精神障礙或其他心智缺陷，致其為意思表示或受意思表示，或辨識其意思表示效果之能力，顯有不足者，法院得因本人、配偶、四親等內之親屬、最近一年有同居事實之其他親屬、檢察官、主管機關或社會福利機構之聲請，為輔助之宣告。

Person requiring assistance: a person whose decision making ability is impaired due to metal and cognitive impairments, or a person who cannot sufficiently express his/her decisions and understand the consequence of his/her decisions. The court of law shall proclaim the person to be in need of assistance as requested by the person's relatives, spouse or relatives closest to the fourth degree, other relatives who are currently or have co-habitated with the person within the latest one year, prosecutors, competent authority agencies or social welfare institutions.

5.4.59 多中心研究計畫：一個以上的醫療機構共同執行的臨床試驗。因為涉及不同的醫療機構，通常需要有專責的協調中心（coordinating center）或協調人員（coordinator），來負責各機構主持人間充分的協調與合作，以保持試驗的一致性

Multi-center study protocol: a clinical trial jointly conducted by more than one medical institutions. Because the trial involves different medical

institutions, a coordinating center or coordinator is needed to ensure that the coordination and cooperation between the different investigators of the participating institutions are consistent and smooth.

5.4.60 無顯著風險醫療器材(低風險性)：沒有顯著風險的實驗醫療器材。

Medical device(s) with no significant risks (low risk): trial medical devices that do not have significant risks.

5.4.61 有顯著風險醫療器材(中風險性、高風險性)：指實驗醫療器材 (1)可能對受試者的健康、安全或福祉產生嚴重的傷害。(2)為促使人體生命延續,而可能對受試者的健康、安全或福祉產生嚴 重的傷害。(3)用於疾病的診斷、減緩、治療或避免惡化,而可 能對受試者的健康、安全或福祉產生嚴重的傷害。

Medical device(s) with significant risk (medium or high risks): medical devices that (1) may cause serious damages to the health, safety and welfare of the subject. (2) may cause serious damages to the health, safety and welfare of the subject in the attempt to prolong human life. (3) may cause serious damages to the health, safety and welfare of the subject in the attempt to diagnose, alleviate, treat or prevent worsening of the disease condition.

5.4.62 受試者同意書：受試者於受告知並了解將參與之臨床試驗之相 關訊息,且參酌是否參與試驗之所有因素後,自願簽署願意參 加試驗之文件。

Informed consent form: A document provided to the subjects informing them about the purposes and process of the clinical trial. After learning

about the details of the trial, subjects will make their decision on whether to participate in the trial or not, and sign the consent form to provide their agreement.

5.4.63 試驗機構：執行臨床試驗之醫療機構。

Trial institution: medical institution that executes the clinical trial.

5.4.64 試驗主持人：試驗機構執行臨床試驗之負責人。

Investigator: person responsible for carrying out the clinical trial at the trial institution.

5.4.65 試驗委託者：臨床試驗之發起及管理者。

Sponsor: party that initiates and manages the clinical trial.

5.4.66 試驗計畫書：記載臨床試驗之目的、設計、方法、統計考量與 編制等事項之文件,並得載明試驗之相關背景及理論。

Protocol: document that contains the purposes, designs, methods, statistical analysis and organization of the clinical trial, including the background information and theories.

5.4.67 主持人手冊：有關試驗藥品之臨床及非臨床數據之編輯物。

Investigator’s brochure: document that listed clinical and non-clinical data of the trial medication.

5.4.68 IRB 委員：參與 IRB 所有活動的成員,委員組成須符合「人體研究倫理審查委員會組織及運作管理辦法」

IRB committee member: a person participating in all activities of the IRB. The composition of the committee must comply with the Regulations

Governing the Organization and Operational Management of the Institutional Review Board for Human Subject Research.

5.4.69 IRB 工作人員：協助委員會之運作的成員。

IRB staff member: personnel assisting in the operation of the IRB.

5.4.70 規範：對於作業或程序的基本要求,提供執行人員依循的準則。

Regulations: a set of standards governing the basic requirements of all operation and procedures and is provided to the executing personnel.

5.4.71 保密協議：指秘密或不公開協議，用來保護研究資訊,使其他接觸資料者不致於濫用。在保密性協議下，任何類型的資訊都須被保密。協議必須建立在某段期間內，在該段期間內需維持資料的保密性

Confidentiality agreement: Private and confidential accords to protect the study information and to prevent misuse of the data by other users. All types of information are protected under the confidentiality agreement. The agreement is established within a set interval, during which confidentiality of the information is maintained.

5.4.72 初審審查意見表：委員初次審查計畫案,所使用之意見表，為計畫審查的正式記錄

Initial reviewer's comments: comment form used by the committee members when first reviewing the protocol, and is a part of the official record of the protocol review.

5.4.73 記錄：不論形式包括如：紙本、電子郵件、傳真、錄音帶及錄影帶等。

Record: regardless of the record form, including paper documents, e-mails, facsimile, audio tapes and video tapes.

5.4.74 期中報告：經核准的研究計畫案之執行進度與狀況報告。

Interim report: approved report on the current progress and status of the study protocol.

5.4.75 暫停：經核准的研究計畫案,主管機關/機構/試驗委託者/試驗主持人/IRB 發現試驗執行中有安全疑慮,須進一步評估,得以主動或被動暫時停止執行部分或全部研究計畫。

Suspension: direct or indirect temporary termination of all or part of the approved study protocol by the competent authority agency/institution/sponsor/investigator/IRB due to safety concerns of the study in progress. The study will also undergo further assessment of its safety.

5.4.76 終止：經核准的研究計畫案,主管機關/機構/試驗委託者/試驗主 持人/IRB 發現試驗執行中有顯著事件發生(例如：確認療效不佳 或安全有疑慮...等),得以主動或被動停止全部研究計畫,不再進行。

Termination: direct or indirect permanent termination of all parts of the approved study protocol by the competent authority agency/institution/sponsor/investigator/IRB, due to occurrence of significant events (For example: confirmed ineffective therapeutic efficacy or safety concerns).

5.4.77 疑似非預期嚴重不良反應 (Suspected Unexpected Serious Adverse Reaction, SUSAR)：指與試驗相關之非預期嚴重藥品不良反應。

Suspected Unexpected Serious Adverse Reaction (SUSAR): any unforeseen and serious adverse drug reactions related to the clinical trial.

5.4.78 實地訪視：IRB 或其代表們所執行的行動,現場訪視研究單 位,評估計畫主持人及機構執行情況,如何照顧研究對象、記 錄資料及通報發現,尤其是研究期間所發生的嚴重不良反應事件。

Site visit: the act taken by the IRB and its representatives to visit the research unit in person, assessing how the principal investigators and the study institution take care of the research subjects, record data and report findings, especially of SAEs that occurred during the study period.

5.4.79 不遵從：不遵守國內/國際人體試驗相關法規、IRB 的政策或 人委會的要求或決定執行研究。

Non-compliance: the act of implementing research trials without complying with the domestic/international regulations on human clinical trials, IRB policies, decisions or requests of the IRB.

5.4.80 嚴重事件：指其事件影響研究的風險與利益,可能影響受試者 安全及繼續參與研究之意願。

Serious event: an event that significantly affects the risks and benefits of the study and will impact the safety of the subject, as well as his/her willingness to continue in the study.

5.4.81 輕微事件：指其事件不影響受試者安全及繼續參與研究之意願。

Mild event: an event that does not affect the safety of the subject and his/her willingness to continue in the study.

5.4.82 持續事件：指事件如果繼續發生,很可能會增加受試者的風 險,影響受試者參與試驗的權利、福祉及安全之風險增加或對研究的科學完整性有不良影響。

Sustained event: an event that if allowed to continue, may increase the risks of the subject, and impact his/her rights, benefits and safety, or adversely affects the scientific integrity of the study.

5.4.83 執行中之研究計畫檔案：各項目前已通過的計畫之計畫書、支 持性文件和報告。

Active study protocol files: refers to study protocols, supportive documents and reports that have been approved and are currently in progress.

5.4.84 非活動之研究計畫檔案：係指目前已無再執行之研究計畫案, 包含結案、終止、或撤案。

Inactive study protocol files: refers to study protocols that are not currently in progress, including completed studies, terminations and withdrawals.

5.4.85 會議記錄：是指由適當組成(有法定人數出席)的 IRB 審查會 議的正式紀錄,其中記載了議程所列的事件、活動及行動。會 議記錄完整地標示出每一項計畫書及(或)活動,並記錄各項 表決的結果。委員會對送交審查的每份計畫組套或個別項目分 別表決：計畫書、受試者同意書、主持人及宣傳資料。紀錄採不記名方式,註明了核准、反對和棄權的票數,以及棄權的理由。

Meeting minute: refers to the official record of the IRB meetings as attended by appropriate parties (quorum attendance). The record should contain the events, activities and actions of the meeting agenda, and completely indicate the protocols and (or) activities and results of each

voting processes. The IRB will vote on each of the submitted protocol or individual components, e.g. protocol, informed consent form, investigator brochure and promotional material. The minute records the results of the voting processes anonymously, and indicates clearly the vote counts for approval, objection, abstention and reasons for abstention.

5.4.86 近親：指其配偶及子女

Close relatives: refers to spouse or children of the subject.

6. 附件 Attachments

無 NA