1.目的 Purpose

為提供人體試驗審查委員會(以下簡稱人委會) 審查資料及安全監測計畫（Data and Safety Monitoring Plan，DSMP）之必要性，於審查發現申請研究計畫案應具 DSMP 時，要求試驗計畫主持人建置該 DSMP 並確實執行；當申請案具 DSMP 時則予以審查；當研究計畫複雜或風險較高時，研究倫理委員會可視需要要求設置資料及安全性監測委員會(Data and Safety Monitoring Board，DSMB)，以落實受試者保護安全機制與資料的完整性。

To provide the Institutional Review Board (hereinafter referred to as “IRB”) the necessity of review data and Data and Safety Monitoring Plan (DSMP), if the IRB believes that the applied study requires DSMP, the PI will be requested establishing DSMP and complying with all regulations. If the application already has DSMP, the IRB will review the DSMP accordingly. For complicated or high-risk studies, the REC will establish Data and Safety Monitoring Board (DSMB) if necessary to achieve the subject protection and safety mechanisms and the integrity of the data.

2.適用範圍 Scope

本標準作業程序包含需建置 DSMP 之研究範圍以及 DSMP 之審查。需建置 DSMP 之研究計畫範圍包括:

This SOP consists of the research scope of DSMP and the review of DSMP. Studies require establishing DSMP are as follows:

2.1 醫療法第八條規範之「新藥、新醫療器材、新醫療技術」之人體試驗 (如：本國未上市新藥、新醫療器材之查驗登記與學術研究案，需提報衛生署審查之新醫療技術案)。

Human studies involving “new drugs, new medical devices, and new medical

technology" regulated in Article 8 of Medical Care Act (e.g. the registration and academic research of the unlisted new drugs and new medical devices in Taiwan shall be reported to MOHW for reviewing the new medical technology).

2.2 研究對象為易受傷害族群 (例如：未成年人、受刑人、原住民、孕婦、精神病人等) 之介入性研究。

It is an interventional study involving vulnerable population (e.g. minors, prisoners, indigent, pregnant women, patients with psychiatric issues, etc.)

2.3 非屬一、二項但顯著超過最小風險 (more than a minor increase over minimal risk) 之研究 (如：盲性試驗、多中心介入性臨床試驗、尤其是其研究指標涉及死亡率及嚴重殘疾發生率之比較)。

Studies not belong to point 2.1 or 2.2, but have more than a minor increase over minimal risk (e.g. blind study, multicenter interventional clinical trial, especially end points involving comparisons between mortality rate and severe disability incidence).

2.4 由高醫體系計畫主持人主導之多機構合作臨床試驗

This is a multiple sites collaboration clinical trial led by the PI affiliated in KMUH system.

2.5 計畫主持人自行評估「風險利益比」(risk/benefit ratio) 後，若案件符合準則需主動提出 DSMP。

After self-evaluating the "risk/benefit ratio", the PI will actively propose DSMP if the ratio has met the criteria.

3.參考文件 References

3.1 藥品優良臨床試驗準則(GCP) (103 年 10 月)

Guidelines of Good Clinical Practice (October 2014)

3.2 藥品優良臨床試驗規範 (2002 年 08 月)

Regulations for Good Clinical Practice (August 2002)

4.名詞定義 Terminology

4.1 資料及安全性監測計畫（Data & Safety Monitoring Plan）：為一風險管理機制，主持人應先預估研究風險並規劃解決對策，以確保受試者保護之充足與適當性。研究倫理委員會於審查計畫時評估該申請研究計畫案應具備 DSMP 時，得要求主持人建置 DSMP 並確實執行；當申請案具備 DSMP 時，委員會亦需予以審查之。

Data & Safety Monitoring Plan (DSMP): is a risk management mechanism. The PI shall estimate study risks in advance and plan for resolutions to ensure the sufficiency and adequacy of subject protection. If the REC decides that the applied study shall have DSMP when reviewing the study, the PI may be requested to establish DSMP and comply all the regulations. If the application already has DSMP, the reviewers will need to review accordingly as well.

4.2 資料及安全性監測委員會（Data & Safety Monitoring Board）：由試驗委託者或計畫主持人所成立之獨立的數據監測委員會，定期評估研究計畫的進度、安全性數據與重要的療效指標。

Data & Safety Monitoring Board (DSMB): is an independent Data & Safety Monitoring Board established by the Sponsor or the PI, which will regularly assess the progress, safety data and important efficacy index of the study.

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
提出計畫送審 Submit study protocol for review	計畫主持人 Principal Investigator	資料與安全性監測計劃(DSMP) Data and Safety Monitoring Plan (DSMP)
評估是否須設置DSMP 或審查提出之DSMP Evaluate whether it is required to establish DSMP or review the proposed DSMP	計畫主持人/委員 Principal Investigator/Committee member	
是否通過「資料及安全性監測計畫」 Has the "DSMP" been approved	委員/專家 Committee member/Expert	新案審查表 New Application Review Form

5.2 職責 Responsibilities

5.2.1 試驗計畫主持人：應主動監測試驗之執行，並於需要時建置 DSMP，必要時應設置 DSMB。

Principal Investigator: shall actively monitor the implementation of the study and establish DSMP or DSMB if necessary.

5.2.2 審查委員/專家：於審查新申請研究計畫案件時應考量試驗監測之適當性，並得要求試驗計畫主持人建置 DSMP 或設置 DSMB。

Reviewers/Experts: the adequacy of study monitoring shall be considered when reviewing the new application. The PI may also be requested to establish DSMP or DSMB.

5.3 流程 Process

5.3.1 計畫主持人提出新案申請：計畫主持人於送審研究計畫時應先自行評估風險，並於研究計畫申請書之臨床試驗基本資料填寫是否有 DSMP 或 DSMB。需建置 DSMP 之臨床研究需一併填寫資料及安全性監測計

畫。

The PI submits a new application: the PI shall self-evaluate the risks when submitting the study protocol and report whether the DSMP or DSMB exists when filling in the basic data of the clinical trial application form. Clinical research that requires DSMP shall also provide relevant information and DSMP.

5.3.2 人體試驗委員會受理送審文件，一般初審計劃案件送審流程，計畫案的初審。

The IRB will receive submitted files, and send for initial review by following the regular initial review process.

5.3.3 審查委員/專家審查研究計畫：審查委員/專家於審查研究計畫時應評估計畫之風險程度。研究計畫需要 DSMP 時，得要求申請人建置 DSMP。若研究計畫已有 DSMP，則需審查 DSMP 內容之適當性。若 DSMP 並未建置 DSMB，審查委員/專家得視個案狀況要求計畫主持人建置 DSMB。

Reviewers/Experts reviewing study protocols: Reviewers/experts shall evaluate risk levels of the study when performing the review. If the study requires DSMP, the applicant is required to establish DSMP. If the study already has DSMP, the adequacy of the DSMP shall be reviewed. If the DSMP does not contain DSMB, reviewers/experts may ask the PI to establish DSMB depending on individual cases.

5.3.4 提供人體試驗委員會決定是否通過研究計畫：人委會於研究計畫審查完成後將結果通知計畫主持人。

For IRB to decide whether the study shall be approved: the IRB will report the review results to the PI after the review process has been completed.

6.附件 Attachment

6.1 附件一 (KMUH/IRB/AF/3.2-01/11.0) 資料與安全性監測計劃(DSMP)

Attachment 1 (KMUH/IRB/AF/3.2-01/11.0) Data and Safety Monitoring Plan (DSMP)