中醫藥應用調研及研究資助計劃（B2 計劃）

申請機構須知

1. 申請機構在提交 B2 計劃的申請時，須先細閱 B2 計劃的申請指引，並符合指引內有關的要求。
2. 為致力遵守最高標準的研究誠信及透明度，所有申請機構在制定研究計劃時，須按研究設計類別參照在「EQUATOR 網絡」[1]列載的報告指南，並確保研究計劃書中列出清楚、完整且準確的研究方法。具體方法如下：
   - 申請機構須熟悉計劃書內與研究設計相關的具體報告指南，有關指南可自行在「EQUATOR 網絡」的網站上搜尋及下載(https://www.equator-network.org/)；
   - 申請機構須在計劃書中附上按研究計劃填寫的完整指南檢查表，並清楚描述研究方法如何與指南對應；
   - 須在計劃書中列明所遵循的特定報告指南，內容須包括報告指南名稱和版本，或任何有助執行機構在審批時能驗證申請機構有否遵循指南的資訊；及
   - 以下列出了常見研究設計的報告指南清單以供參考，研究設計須同時參照中醫藥發展基金（基金）相應的評審要求（如有）：

研究設計 Study design	報告指南名稱 Title of the reporting guideline	Pubmed 連結 Pubmed Links	其他評審要求
橫斷面研究／問卷調查 Cross-sectional study / survey	A Consensus-Based Checklist for Reporting of Survey Studies (CROSS)	https://pubmed.ncbi.nlm.nih.gov/33886027/	
觀察性研究 Observational studies	The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies	https://pubmed.ncbi.nlm.nih.gov/18064739/	
	The reporting of studies conducted using observational routinely collected health data statement for pharmacoepidemiology (RECORD-PE)	https://pubmed.ncbi.nlm.nih.gov/30429167/	

[1] EQUATOR (Enhancing the QUAlity and Transparency Of Health Research) 網路是一項國際計劃，旨在透過推廣透明、準確的報告，以及更廣泛地使用整全的報告準則，來提高已發表的優質研究文獻之可靠性和價值。(https://www.equator-network.org/)。

	The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) statement	https://pubmed.ncbi.nlm.nih.gov/26440803/	
隨機對照試驗 Randomized trials	Standard Protocol Items for Clinical Trials with Traditional Chinese Medicine 2018: Recommendations, Explanation and Elaboration (SPIRIT-TCM Extension 2018)	https://pubmed.ncbi.nlm.nih.gov/30484022/	須同時參照「申請進行隨機對照試驗的注意事項」
	Revised STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): extending the CONSORT statement	https://pubmed.ncbi.nlm.nih.gov/20543992/	
	CONSORT Extension for Chinese Herbal Medicine Formulas 2017: Recommendations, Explanation, and Elaboration	https://pubmed.ncbi.nlm.nih.gov/28654980/	
	CONSORT extension for reporting N-of-1 trials for traditional Chinese medicine (CENT for TCM) : Recommendations, explanation and elaboration	https://pubmed.ncbi.nlm.nih.gov/31519276/	
	Standards for reporting interventions in clinical trials of cupping (STRICTOC): extending the CONSORT statement	https://pubmed.ncbi.nlm.nih.gov/32021646/	
系統綜述 Systematic reviews	Reporting items for systematic reviews and meta-analyses of acupuncture: the PRISMA for acupuncture checklist	https://pubmed.ncbi.nlm.nih.gov/31405367/	
	PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) Extension for Chinese Herbal Medicines 2020 (PRISMA-CHM 2020)	https://pubmed.ncbi.nlm.nih.gov/32907365/	
	PRISMA extension for moxibustion 2020: recommendations, explanation, and elaboration	https://pubmed.ncbi.nlm.nih.gov/33100229/	
臨床實踐指南 Clinical Practice Guideline	RIGHT for acupuncture: An extension of the RIGHT statement for clinical practice guidelines on acupuncture	https://pubmed.ncbi.nlm.nih.gov/34091023/	須同時參照「中醫藥臨床路徑／指南相

	The RIGHT Extension Statement for Traditional Chinese Medicine: Development, Recommendations, and Explanation	https://pubmed.ncbi.nlm.nih.gov/32889127/	關項目評審範疇」
質性研究 Qualitative research	Standards for reporting qualitative research: a synthesis of recommendations	https://pubmed.ncbi.nlm.nih.gov/24979285/	
人工智慧和機器學習研究 Artificial Intelligence and Machine Learning Studies	Guidelines for clinical trial protocols for interventions involving artificial intelligence: the SPIRIT-AI extension	https://pubmed.ncbi.nlm.nih.gov/32908284/	
	TRIPOD+AI statement: updated guidance for reporting clinical prediction models that use regression or machine learning methods	https://pubmed.ncbi.nlm.nih.gov/38626948/	
	Consolidated Reporting Guidelines for Prognostic and Diagnostic Machine Learning Modeling Studies: Development and Validation	https://pubmed.ncbi.nlm.nih.gov/37651179/	
	MINIMAR (MINimum Information for Medical AI Reporting): Developing reporting standards for artificial intelligence in health care	https://pubmed.ncbi.nlm.nih.gov/32594179/	
	Reporting guideline for the early-stage clinical evaluation of decision support systems driven by artificial intelligence: DECIDE-AI	https://pubmed.ncbi.nlm.nih.gov/35585198/	
	Minimum information about clinical artificial intelligence modeling: the MI-CLAIM checklist	https://pubmed.ncbi.nlm.nih.gov/32908275/	
教育研究 Education research	SQUIRE-EDU (Standards for QUality Improvement Reporting Excellence in Education): Publication Guidelines for Educational Improvement	https://pubmed.ncbi.nlm.nih.gov/30998575/	

服務品質改善研究 Service quality improvement studies	SQUIRE 2.0 (Standards for QUality Improvement Reporting Excellence): revised publication guidelines from a detailed consensus process	https://pubmed.ncbi.nlm.nih.gov/26369893/	
經濟評估 Economic evaluations	Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022) Statement: Updated Reporting Guidance for Health Economic Evaluations	https://pubmed.ncbi.nlm.nih.gov/35031096/	

- 在某些情況下，申請機構可能需要參照多份報告指南以確保研究報告的全面性。例如在撰寫針灸隨機對照試驗時，需使用 SPIRIT-TCM Extension 2018 作整體設計的參考，並同時使用 STRICTA 撰寫針灸治療的詳細方案，以便日後臨床醫師作參考。又例如在設計質性 – 橫斷面研究時，需同時參考 CROSS 以及 Standards for reporting qualitative research: a synthesis of recommendations，以確保混合方法研究的步驟透明清晰。

3. 申請機構須在支出預算中，列明與依從報告指南而衍生支出的理據，例如培訓及購買專用軟件等。

4. 如未能參照「EQUATOR 網絡」列出的報告指南撰寫研究計劃，該申請可能會被視為未能符合審批準則。就「EQUATOR 網絡」上沒有載列相應報告指南的研究設計，申請機構應參考在已發表文獻中的其他既定標準。

5. 如項目成功獲批准，研究結果也應根據相關報告指南撰寫。所有申請機構必須高度重視其研究報告的透明度、準確性和完整性，以確保其研究結果的可信程度，可重複性及臨床可用性。

6. 申請機構有責任按需要就研究項目向有關監管機構申請核准／證明(包括與倫理、試驗藥物的使用、安全及／或存取第三方資料相關的批准等)。如在截止申請日期前仍未取得有關批准，申請機構應在計劃書中說明有關申請的計劃和進度。如有關研究申請項目獲批准，申請機構應在 12 個星期內（或基金指明的時間）提交有關批准／證明。如未能按時提交，將被視作放棄基金的資助。此外，申請機構須確保所獲得的有關批准／證明與基金所批核的項目名稱相同，且有關批准所包括的研究方案內容必須與提交予基金審批的內容一致。

7. 基金將適時就本須知作出修訂。

中醫藥發展基金執行機構
2024 年 10 月