Research Proposal Template 研究計劃書模板

有	無	內容
☐	☐	**中/英文題目名稱 Title**
☐	☐	**主要主持人及協同主持人姓名 Principle or Co-principle investigators**
☐	☐	**背景/問題陳述 Background/Problem Statement** Provide an introduction and background information. Describe past research and/or findings leading to the formulation of your study.
☐	☐	**研究目的 Objectives** List your research objectives, provide justification for the research, and explain how you will use the data. You may reference grant application pages and attach as an appendix. For IRB purposes, the protocol cannot be your grant application.
☐	☐	**研究方法與設計 Study Design/Methodology** • Sample selection and size (number of participants, age range, health status—Inclusion/Exclusion Criteria) • Describe the proposed intervention (if applicable) • Data collection procedures, instruments used, and methods for data quality control. • Randomization information (if applicable) • Study timeline (if study is greater than minimal risk).
☐	☐	**参与者招募方法 Participant Recruitment Methods** Describe plans for the identification and recruitment of participants, including how the population will be identified, and how initial contact will be made with potential participants by those having legitimate access to the participants' identity and the participants' information. Describe the setting in which an individual will be interacting with an investigator, when applicable. Describe how recruitment materials will be used.
☐	☐	**知情同意過程 Informed Consent Process** Describe the consent procedures to be followed, the circumstances under which consent will be sought and obtained, the timing of obtaining informed consent, whether there is any waiting period between informing the prospective participant and obtaining consent, who will seek consent when applicable. If requesting a waiver/alteration to the consent process or waiver of documentation of informed consent (waiving signature), state that here and include the rationale for doing so. • 签署知情同意书 - 风险大于最小风险的研究必须签署知情同意书。 • 未签署的知情同意书（又称前言 Preamble）- 用于符合规定中列出的特定标准的最低风险研究。一般用于调查、焦点小组和访谈研究，但也可用于 伦理审查小组 认为合适的其它情况。 • 免除知情同意--用于风险极低的研究，在这种情况下获得同意是不现实的，并且符合法规中的特定标准。一般用于使用回顾性数据和/或标本的研究。

☐	☐	**資料程序 Research Procedures** Describe the research procedures that will be followed. Identify all procedures that will be carried out with each group of participants. Differentiate between procedures that will be performed specifically for this research project. Include a schedule of events, if applicable.
☐	☐	**風險考量 Minimizing Risks** Describe the procedures for protecting against or minimizing any potential risks, including risks of breach of confidentiality or invasion of privacy. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of participants (required for studies greater than minimal risk). If the study involves investigational drugs or devices, explain the process for storing and releasing (e.g. pharmacy oversight, device management, etc).
☐	☐	**數據分析計畫 Plan for Analysis of Results** • Methods and models of data analysis according to types of variables • Programs to be used for data analysis
☐	☐	**研究數據/資料、紀錄和隱私保管 Research Materials, Records, and Privacy** Describe the data you plan to collect for this study and include the following details as appropriate: • Specify what information will be recorded, and if the data is existing or created for research. • List the sources of research material obtained. • Explain why this information is needed to conduct the study. • Specify who has access to the data, where the data will be stored, and how the researcher will protect both the data and the participant with respect to privacy and confidentiality. Include information about what software or program will be used to store data. This includes software such as Microsoft Excel, Onedrive, SPSS, etc. • Address physical and electronic data security measures (e.g., locked facility, limited access), data security (e.g., password-protection, data encryption), and other safeguards to protect identifiable research information (e.g., coding or links). • Specify how the data will be de-identified (if applicable).
☐	☐	**文獻/其它資料 References**