

**受美國衛生福利部(DHHS)或美國食品藥物管理局(FDA)管轄計畫
申請免審之理由勾選表**

請逐項勾選：

一、研究案件是否以未成年人、收容人、原住民、孕婦、身心障礙、精神病患、受拘禁人、判斷受不當脅迫或無法以自由意願做決定者之研究對象。

否

是(勾選此項並不符合免審範圍)： 未成年人(20歲以下) 收容人
 原住民 孕婦 身心障礙 精神病患 無法自主行使同意之成人
 受拘禁人

二、請勾選自評符合之項目(需符合以下項目之一)，是否符合免審範圍由本院研究倫理委員會判定：

於公開場合進行之非記名、非互動且非介入性之研究，且無從自蒐集之資訊辨識特定之個人。

請說明理由：_____

使用已合法公開週知之資訊，且資訊之使用符合其公開週知之目的。

請說明理由：_____

公務機關執行法定職務，自行或委託專業機構進行之公共政策成效評估研究。

請說明理由：_____

於一般教學環境中進行之教育評量或測試、教學技巧或成效評估之研究。此研究不太可能對學生學習所需教育內容的機會或評估提供教學的教育者產生不利影響。

請說明理由：_____

註：如果涉及以下方式，不能免審：例如新的教育策略、隨機或立意分派學生到不同的教育組別、體育課涉及極限運動。

研究計畫屬最低風險，且其研究對象所遭受之風險不高於未參加該研究者，經本會評估得免審查。若免審列舉項目同時符合簡易審查項目，則優先適用免審。

前項最低風險，係指研究對象所遭受之危害或不適的機率或強度，不高於日常生活中遭受的危害或不適。

※屬於免審項目列舉如下：

1. 研究僅包括涉及教學測試（例如認知，診斷，能力，成就）、問卷調查程序，訪談程序或觀察公共行為（包括視覺或聽覺記錄）的互動且符合以下條件(美國法規 45CFR46 §46.104 d(2))：

(i) 研究者以不可直接或間接識別受試者個人身分之記錄方式收集資訊

(ii) 研究對象於研究中的回應在研究外揭露時，不會使其受到刑事或民事訴訟，或損及其經濟、就業、教育進修、或聲譽。

2. 研究涉及良性行為介入並以口頭、書面（包括數據輸入）或視聽記錄收集其資訊，受試者事前同意此介入及資訊之收集且符合以下條件(美國法規 45CFR46 §46.104 d(3))：

(i) 研究者以不可直接或間接識別受試者個人身分之記錄方式收集資訊

(ii) 研究對象於研究中的回應在研究外揭露時，不會使其受到刑事或民事訴訟，或損及其經濟、就業、教育進修、或聲譽。

<註> 良性行為介入(benign behavioral interventions)指良性的、有利的、有益健康的、溫和的，持續時間短、無害、無痛、無物理侵入、不太可能對受試者產生顯著的不良持久影響，此介入不會讓受試者感到不舒服(令人反感或令人尷尬)。

舉例：1. 音樂介入、溫和的運動介入等 2. 讓受試者玩線上遊戲，讓他們在各種噪音條件下解決謎題，或者讓他們決定如何在他們自己和其他人之間分配名義數量的收到的現金。

3. 無可辨識個人資料之次級資料研究

請說明符合本項理由(若符合列舉事項請明列符合項次，若未符合列舉事項，請說明研究符合屬最低風險，且其研究對象所遭受之風險不高於未參加該研究者之理由，以供本會評估是否符合)：

三、除了須符合前項條件，屬美國衛生福利部(DHHS)或美國食品藥物管理局(FDA)管轄之計畫，若自評符合附件情形之一，請勾選，是否符合免審範圍由本院研究倫理委員會判定：

<input type="checkbox"/>	<p>CATEGORY 1</p> <p>1. The research is conducted in established or commonly accepted educational settings.</p> <p>2. The research involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction, such as:</p> <p style="padding-left: 40px;">(1) Research on regular and special education instructional strategies.</p> <p style="padding-left: 40px;">(2) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.</p> <p>3. The research is not regulated by the US FDA.</p>
<input type="checkbox"/>	<p>CATEGORY 2</p> <p>1. The research only involves interactions involving one or more of the following:</p> <p style="padding-left: 40px;">(1) Educational tests (cognitive, diagnostic, aptitude,</p>

	<p>achievement).</p> <ol style="list-style-type: none"> (2) Survey procedures. (3) Interview procedures. (4) Observation of public behavior (including visual or auditory recording). <p>2. One of the following conditions are met:</p> <ol style="list-style-type: none"> (1) The information obtained is recorded in such a manner that participants cannot be identified, directly or indirectly through identifiers linked to the participants. (2) Any disclosure of the participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation. <p>3. The research is not regulated by the US FDA.</p>
<input type="checkbox"/>	<p>CATEGORY 3</p> <p>Research involving benign behavioral interventions in conjunction with the collection of information from an adult participant through verbal or written responses (including data entry) or audiovisual recording if the participant prospectively agrees to the intervention and information collection.</p> <ol style="list-style-type: none"> 1. Benign behavioral interventions are: <ol style="list-style-type: none"> (1) Brief in duration. (2) Harmless. (3) Painless. (4) Not physically invasive. (5) Not likely to have a significant adverse lasting impact on the participants. 2. The researcher has no reason to think the participants will find the interventions offensive or embarrassing. 3. At least one of the following criteria is met: <ol style="list-style-type: none"> (1) The information obtained is recorded by the investigator in such a manner that the identity of the human participants cannot readily be ascertained, directly or through identifiers linked to the participant; or (2) Any disclosure of the human participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational

	<p>advancement, or reputation; or</p> <p>(3) If the information obtained is recorded by the investigator in such a manner that the identity of the human participants can readily be ascertained, directly or through identifiers linked to the participants, an IRB conducts a limited IRB review and determines, when appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.</p> <p>4. If the research involves deception of participants regarding the nature or purposes of the research: The participant authorizes the deception through a prospective agreement to participate in research in circumstances in which the participant is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.</p> <p>5. The research is not regulated by the US FDA.</p>
<input type="checkbox"/>	<p>CATEGORY 4</p> <p>Secondary research for which consent is not required, that uses of identifiable private or identifiable biospecimens, if at least one of the following criteria are met:</p> <ol style="list-style-type: none"> 1. The identifiable private information or identifiable biospecimens are publicly available. 2. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects. 3. The research involves only information collection and analysis involving the researcher's use of identifiable health information regulated under HIPAA for the purposes of "health care operations" or "research" or "public health activities and purposes" as defined in HIPAA. 4. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the

	<p>E-Government Act of 2002, 44 U.S.C. 3501 or Privacy Act of 1974, 5 U.S.C. 552a., and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501</p> <p>5. The research is not regulated by the US FDA.</p>
<input type="checkbox"/>	<p>CATEGORY 5</p> <ol style="list-style-type: none"> 1. The project is a research or demonstration project. 2. The research is conducted by or subject to the approval of a US federal government Department or Agency head (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects). 3. The research is designed to study, evaluate, improve, or otherwise examine a program that delivers a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act) and includes one or more of the following: <ol style="list-style-type: none"> (1) Procedures for obtaining benefits or services under those programs. (2) Possible changes in or alternatives to those programs or procedures. (3) Possible changes in methods or levels of payment for benefits or services under those programs. 4. The research is conducted pursuant to specific statutory authority of the US federal government. 5. There is no statutory requirement that an IRB or EC review the research. 6. For US government agencies, the agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site a list of research and a list of the research and demonstration projects prior to commencing the research involving human subjects. 7. The research does not involve significant physical invasions or intrusions upon the privacy of participants. 8. The research does not involve prisoners, except for research aimed at involving a broader participant population that only incidentally includes prisoners.

	<p>9. The research is not regulated by the US FDA.</p>
<input type="checkbox"/>	<p>CATEGORY 6</p> <p>1. The research involves taste and food quality evaluation or is a consumer acceptance study.</p> <p>2. Either of the following is true:</p> <p>(1) Wholesome foods without additives are consumed.</p> <p>(2) If a food is consumed that contains a food ingredient or an agricultural chemical or environmental contaminant, the food ingredient or agricultural chemical or environmental contaminant is at or below the level and for a use found to be safe by one of the following:</p> <p>(3) The Food and Drug Administration.</p> <p>(4) The Environmental Protection Agency.</p> <p>(5) The Food Safety and Inspection Service of the U.S. Department of Agriculture.</p>

計畫主持人簽章：

日期：