文件名稱	人體研究計畫免審作業程序書			權責單位	研究倫理委員會行政中心	頁碼/總頁數	1/7
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一、目的

本標準作業程序依衛生福利部公告之人體研究法第五條及「得免倫理審查委員會審查之人體研究案件範圍」規範，提供人體研究計畫案免審的規範及管理原則。台大醫院之人體研究若符合免審條件，須由研究倫理委員會判定。若非人體研究之範圍，不需送研究倫理委員會判定。

二、範圍

(一)依衛生福利部公告之人體研究法第五條及「得免倫理審查委員會審查之人體研究案件範圍」規範，執行人體研究非以未成年人、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為研究對象，且符合下列情形之一，得免本會審查，並由本會核發免審證明：

1. 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。
2. 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。
3. 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。
4. 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之教育內容的機會或評估提供教學的教育者產生不利影響。
5. 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

   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。若免審列舉項目同時符合簡易審查項目，則優先適用免審。

(二)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，符合附件情形之一，得免本會審查，並由本會核發免審證明。

三、職責

（一）計畫主持人：備齊所需文件，依研究倫理委員會要求提供相關資料。

（二）研究倫理委員會行政中心：確認案件資料、送審案件資料、彙整審查意見並通知計畫主持人及核發免審證明。若計畫案不符免審範圍時，依一般審查或簡易審查程序進行。

（三）研究倫理委員會委員：提供審查意見，判定計畫是否符合免審條件。

（四）研究倫理委員會主任委員：核定申請免審條件計畫審查結果。

四、 流程圖

活動	職責
研究倫理委員會行政中心收件	研究倫理委員會行政中心
↓1 個工作天	
確認資料完整性	研究倫理委員會行政中心
↓1 個工作天	
委員進行審查判定	研究倫理委員會委員
↓7 個天作天	
↓ 符合免審 / ↓ 符合免審，但須修正內容 / ↓ 不符合免審，建議改為簡易審查 / ↓ 不符合免審，改送一般審查	研究倫理委員會委員
↓	
確認無誤後，簽核主任委員，核發免審證明	研究倫理委員會行政中心/主任委員

五、 細則

（一）受理送審文件

1. 研究計畫主持人填寫台大醫院人體研究計畫免審申請書(AF-139)及依申請人體研究計畫免審申請送件核對單(AF-138)檢附文件。
2. 受理計畫案（請見 SOP01100-2-000007）
3. 登錄收件日期及寄發申請案受理信件予計畫主持人。
4. 依案件送件時間安排當週輪值受理案件之研究倫理委員會審查。若因時效或其他重要因素，經主任委員同意後得轉其他研究倫理委員會收案。

（二）免審審查流程

1. 行政中心於收到申請免審計畫案，確認資料完整性後，依各研究倫理委員會簡易審查輪值表送由輪值簡易審查委員進行免審審查。每一計畫案原則由 1 位簡審委員審查，並由簡審委員審查時視需要建議加送

專家審查。若需專家審查，則由主任委員或副主任委員指派。審查者於 7 個工作天內進行判定是否符合免審條件，並將判定結果書寫於免審計畫審查表之審查結果欄位內(AF-140 或 AF-146(若屬受美國衛生福利部(DHHS)或美國食品藥物管理局(FDA)管轄計畫))。

2. 審查結果得為「符合免審」、「符合免審，但須修正內容」、「不符合免審，建議改為簡易審查」、「不符合免審，建議改為一般審查」。審查者不得逕為不通過之決議。
3. 若送審計畫案符合免審，行政中心於 2 個工作天內簽核主任委員後核發免審證明(AF-141)。
4. 若審查結果如為「符合免審，但須修正內容」，則行政中心於 2 個工作天內將審查建議(AF-080)通知計畫主持人後，計畫主持人應於 5 個工作天內回覆，若 10 工作天內未獲得回覆，行政中心需進行催覆，間隔 10 個工作天再催覆 1 次，催覆第 2 次後 10 個工作天仍未回覆者，則逕予撤案，並以書面通知計畫主持人。如計畫主持人有特殊理由者，得申請延長回覆時間。倫委會行政中心於收到回覆審查意見及資料後，確認回覆文件之正確及完整性後，並依修改幅度決定是否再送審查委員進行複審。
5. 如判定不符免審，則視計畫案建議改為簡易審查(見 SOP01100-2-000009)或一般審查 (見 SOP01100-2-000010)進行，並於 2 個工作天內通知計畫主持人，若有修改建議，則送請計畫主持人回覆審查意見。

六、 文件的歸檔

儲存完整文件及其他相關文件。

七、 後續審查

經本會審定之免審案件無須進行後續持續及結案審查，惟計畫執行期間若發生屬非預期、相關及涉及造成受試者或他人更大傷害風險之非預期問題，須向本會通報(見SOP01100-2-000017)。若計畫擬進行變更且超過原免審範圍，計畫主持人須重新以新案送審。

八、 名詞解釋

人體研究：係指從事取得、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。

附件

CATEGORY 1

1. **The research is conducted in established or commonly accepted educational settings.**
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:**
   (1) **Research on regular and special education instructional strategies.**
   (2) **Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.**
3. **The research is not regulated by the US FDA.**

CATEGORY 2

1. The research only involves interactions involving one or more of the following:
   (1) Educational tests (cognitive, diagnostic, aptitude, achievement).
   (2) Survey procedures.
   (3) Interview procedures.
   (4) Observation of public behavior (including visual or auditory recording).
2. One of the following conditions are met:
   (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.
3. The research is not regulated by the US FDA.

CATEGORY 3

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.

1. Benign behavioral interventions are:
   (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:
   (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 advancement, or reputation; or
   (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.

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.

5. The research is not regulated by the US FDA.

CATEGORY 4

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:

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 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**
5. **The research is not regulated by the US FDA.**

CATEGORY 5

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:**
   - **(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.**
9. **The research is not regulated by the US FDA.**

CATEGORY 6

1. The research involves taste and food quality evaluation or is a consumer acceptance study.
2. Either of the following is true:
- **(1) Wholesome foods without additives are consumed.**
- **(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:**
- **(3) The Food and Drug Administration.**
- **(4) The Environmental Protection Agency.**
- **(5) The Food Safety and Inspection Service of the U.S. Department of Agriculture.**