

東海大學非生物醫學類人類研究專題計畫申請研究倫理審查作業辦法

HU Regulations for Research Ethics Review of Non-Biomedical Human Research Projects

2012/06/05 (第 9 次行政會議通過)

Approved by the 9th Administrative Affairs Meeting on June 5, 2012

2013/04/10(第 6 次行政會議修訂通過)

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2022/08/31(第 6 次行政會議修正通過)

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第一條 依據國家科學及技術委員會公告之「推動專題研究計畫研究倫理審查制度第二期試辦方案」，鼓勵本校執行非生物醫學類之人類研究專題計畫送交研究倫理審查，以落實研究參與者之權益保障，特訂定非生物醫學類人類研究專題計畫申請研究倫理審查作業辦法（以下簡稱本辦法）。

Article 1 The THU Regulations for Research Ethics Review of Non-Biomedical Human Research Projects (hereinafter referred to as Regulations) are established in accordance with the Phase II Pilot Program for the Implementation of Research Ethics Review Mechanisms for Research Projects announced by the National Science and Technology Council (NSTC), to encourage the submission of non-biomedical human subjects research projects at THU for research ethics review and to ensure the protection of research participants' rights and interests.

第二條 本辦法所稱之人類研究係以人或群體為對象，使用介入或互動之方法或使用個人資料，而進行與該人或群體有關之系統性調查或專業學科的知識探索活動。
本校涉及人類研究之非生物醫學類專題研究計畫，指定由中區區域性研究倫理中心審查委員會辦理研究倫理審查。

Article 2 For the purposes of these Regulations, the term human research refers to systematic investigations or professional academic explorations involving individuals or groups, conducted through interventions or interactions, or through the use of personal data related to those individuals or groups.
All non-biomedical human subjects research projects conducted at THU shall undergo research ethics review by the Central Regional Research Ethics Center of Taiwan.

第三條 本辦法適用於一〇二年度起，經科技部核定補助（含執行中之多年期計畫）涉及人類研究之非生物醫學類專題研究計畫。

Article 3 These Regulations apply to non-biomedical human subjects research projects funded by the NSTC beginning in 2013 (including ongoing multi-year projects).

第四條 計畫主持人涉及人類研究，須遵守下列事項：

- 一、於專題研究計畫開始執行前，向本校研發處提出研究倫理審查申請，並依照中區區域性研究倫理中心之規定，備齊相關送審資料。
- 二、專題研究計畫於研究倫理審查通過後方可執行。
- 三、計畫主持人開始執行研究計畫後，至研究計畫執行完畢為止，應配合中區區域性研究倫理中心持續追蹤，或不定期訪查等相關程序，以確保執行過程符合研究倫理原則。

- Article 4** Principal Investigators (PIs) conducting human subjects research shall comply with the following:
- I. Prior to the commencement of the research project, the PI shall apply for research ethics review through the Office of Research and Development and submit the required documentation in accordance with the regulations of the Central Regional Research Ethics Center.
 - II. The research project may only commence after receiving approval from the research ethics review.
 - III. From the start of the project until its completion, the PI shall cooperate with ongoing monitoring, occasional audits, or other procedures conducted by the Central Regional Research Ethics Center to ensure compliance with research ethics principles
- 第五條 適用本辦法範疇內之研究計畫，審查費用請計畫主持人於計畫中申請追加經費。其餘計畫類型之審查費收費標準，則依中區區域性研究倫理中心實際公告為準。
- Article 5** For research projects falling within the scope of these Regulations, the PI shall apply for additional funding to cover the research ethics review fee. For other types of projects, please observe the fee schedules announced by the Central Regional Research Ethics Center.
- 第六條 本校推派教師一人，負責與中區區域性研究倫理中心聯繫及協助完成相關業務。
- Article 6** THU shall appoint one faculty member to serve as liaison with the Central Regional Research Ethics Center and assist in handling related affairs.
- 第七條 本辦法經行政會議決議通過後實施。
- Article 7** The Regulations herein shall be promulgated upon approval from the Administrative Affairs Meeting.