

# Regulations for Human Research Ethics Review of National Cheng Kung University

Approved by 165<sup>th</sup> Administrative Meeting on 9 May 2012  
Approved by 169<sup>th</sup> Administrative Meeting on 18 September 2013  
Approved by 183<sup>rd</sup> Administrative Meeting on 16 November 2016  
Approved by 186<sup>th</sup> Administrative Meeting on 20 September 2017

- Article 1 National Cheng Kung University (hereinafter the “University”) has established these Regulations in accordance with the Provisional Regulations of Governance Framework for Human Research Ethics of the University in order to promote applications for human research ethics review by the University.
- Article 2 “Human research” mentioned in these Regulations refers to one of the following:
1. Human subject research referred to in the Human Subjects Research Act involving obtaining, investigating, analyzing, or using human specimens or an individual person’s biological behavior, physiological, psychological, genetic or medical information.
  2. Behavioral scientific research means that individuals or colonies are used as targets and knowledge exploratory activities about systematic investigative or professional disciplines related to these individuals or colonies through the use of intervention or interactive methods or through use of personally identifiable information.
- Article 3 The target of application of these Regulations is human research that is not yet executed and that meets one of the following situations:
1. Human research that is funded by the University.
  2. Human research of which the principal investigator, co-principal investigator, sub-investigator or research team is the staff of the University.
  3. Human research in which staff of the University is responsible for recruitment of research participants or explanation of research details.
  4. Human research in which the staff of the University acquires personally identifiable research data of the research participants for analysis or use.
- Staff of the University under the previous paragraph means full-time teaching researchers (including contracted researchers/staff), staff (including University employees), project staff and students of the University. Any person receiving human research funding from the University may be deemed the staff of the University.
- In the following projects mentioned in the previous two paragraphs and if the Human Subjects Research Act is applicable, the projects shall be submitted to the Institutional Review Board of National Cheng Kung University Hospital or the research ethics committee outside the University for review:
1. Human subject research defined under Article 8 of the Medical Care Act.
  2. Acquisition, investigation, analysis and use of human genes, excluding research project using data from the database of Taiwan Biobank.
  3. Use of hospital patients or their family members thereof as research targets.
  4. Direct use of the hospital’s instruments, images, medical histories or other linked data of similar nature.
- Article 4 The principal investigator whose project is in accordance with the previous two articles shall file an application with the Human Research Ethics Committee of the University (hereinafter the “Ethics Committee”) through submission of below documents:
1. Research Ethics Review Application Form (please log into online application review system <https://rec.chass.ncku.edu.tw/login>; please contact the Ethics

Committee for first-time application) and relevant attachments listed in the application form.

2. Human research proposal.

Upon receipt of the application, the Ethics Committee shall verify the relevant project with the Office of Research and Development of the University before official acceptance of the case.

Other review instructions shall be in accordance with the information announced on the website of the Ethics Committee <https://rec.chass.ncku.edu.tw/>.

Article 5 The ethics review procedure for human research shall be in accordance with the Guidelines for Establishment and Review of Ethics Committee.

Article 6 During ethics review of human research, the applicants may be asked to sit in meetings to provide explanations as required.

Article 7 In accordance with the review experience about the risk of harm that the research participants may suffer and in consideration of the special nature or vulnerability of the research participants and their colonies, the following procedures may be undertaken based on the human research project application:

1. Procedure for review waiver where a review is exempt or a certificate of review waiver is issued.
2. Expedited review procedure with a written review.
3. Full-committee review procedure with both written and meeting reviews.

The Ethics Committee may determine the scope of research cases for which review exemption or expedited review procedure may be applicable under subparagraphs 1 and 2 above based on public announcements made by the Ministry of Education and the Ministry of Health and Welfare, Executive Yuan.

Article 8 The review results by the Ethics Committee are divided into 4 types - approval, approval following amendment, reconsideration following amendment and disapproval. Before accomplishing the review results, a notice shall be given to the principal investigator of the human research project to provide proper explanations. The review results shall be supported by specific grounds and shall be provided to the principal investigator in writing.

Article 9 If a human research project is disapproved by the Ethics Committee in accordance with Article 5 of the Human Subjects Research Act, the University shall not agree to the execution of such this project.

Article 10 If the principal investigator of the human research project submitted for review objects to the review results, he/she may provide grounds to seek reconsideration. There shall be no more than one reconsideration. If the principal investigator still objects to the result of reconsideration, an appeal may be filed with the Human Research Ethics Compliance Committee of the University. There shall be no more than one appeal.

Article 11 After the relevant project is reviewed and approved and starting from its execution, the Ethics Committee shall continue to follow up and help ensure that the execution of the relevant project is consistent with research ethics requirements until accomplishing the analysis of the research participants' identifiable data.

Article 12 The Ethic Committee may charge a review service fee from the relevant project principal investigator for case review. The fee schedule shall be separately stipulated by the Ethics Committee.

Article 13 These Regulations, including any amendment hereto, are implemented following approval by the Administrative Meeting.