

# **The Provisional Regulations of Governance Framework for Human Research Ethics of National Cheng Kung University**

Approved by 164<sup>th</sup> Administrative Meeting on 23 November 2011  
Amendment approved by 165<sup>th</sup> Administrative Meeting on 9 May 2012  
Amendment approved by 169<sup>th</sup> Administrative Meeting on 18 September 2013  
Amendment approved by 173<sup>rd</sup> Administrative Meeting on 24 September 2014  
Amendment approved by 183<sup>rd</sup> Administrative Meeting on 16 November 2016

Article 1 The National Cheng Kung University (hereinafter the “University”) has established the Provisional Regulations of Governance Framework for Human Research Ethics of the University (hereinafter these “Regulations”) to duly perform human research and to protect the interest of the research participants. The Research Center for Humanities and Social Sciences is responsible for conducting the relevant activities before the establishment of the Regulations for Establishment of Research and Academic Ethics Center of the University. These Regulations are not applicable to the Institutional Review Board under National Cheng Kung University Hospital.

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 the use of personally identifiable information.

Article 3 The University has established the committees below with missions to protect the interest of the research participants as following:

1. Research Ethics Advisory Committee: To establish guidelines for promoting research ethics and policies for protecting the interest of the research participants.
2. Research Ethics Committee: To plan and carry out research ethics review and execution matters. More than one research ethics review committee may be established as required for the review. For discussing common standards or relevant matters, joint meetings or chairmen’s joint meetings may be held regularly.
3. Research Compliance Committee:
  - (1) Onsite visit and investigation on whether human research projects are carried out in accordance with the approved details of ethics review.
  - (2) Process complaints from research participants.
  - (3) Process appeals from those who did not pass ethics reviews.
  - (4) Assist the Research Ethics Committee with subsequent handling of relevant audit affairs.

The guidelines for the establishment of the above committees shall be

separately stipulated.

- Article 4 To execute the resolutions of the Research Ethics Advisory Committee, the University may support each Research Ethics Committee and Research Ethics Supervision Committee through the Research Center of Humanities and Social Sciences. As required, researchers with doctoral degrees may be hired to perform research related work such as review, educational training and advisory activities. And full-time administrative staff may be arranged to carry out relevant affairs.  
The staff under the previous paragraph shall accept at least 9 hours of human research ethics related educational training courses every year.
- Article 5 To execute the missions provided in these Regulations, the Research Center of Humanities and Social Sciences shall prepare a Manual of Human Research Ethics Governance Framework of the University. Such manual shall contain the operating procedural regulations for which the Center shall provide assistance and the procedural regulations for the operation of the Research Ethics Committee.  
If the principles and procedures established under the procedural regulations mentioned in the previous paragraph relating to any matter provided in these Regulations or the regulations about the establishment of any committee, such principles and procedures shall be submitted to the Administrative Meeting of the University for approval. The rest shall be submitted to the Research Ethics Committee for discussion and approval. The same shall be applicable to any amendment.
- Article 6 The funding required under these Regulations shall be paid out of the ethics review cost budgeted for human research projects, relevant commission fees and other funds sourced by the University under the principle of self-sustainability.
- Article 7 Any case in breach of academic ethics shall be governed by the Regulations for Establishment and Review of Academic Ethics Review Committee of the University.
- Article 8 These Regulations, including any amendment hereto, are implemented following the approval by the Administrative Meeting.