

Guidelines for Establishment of Human Research Compliance Committee of the National Cheng Kung University

Approved by 166th Administrative Meeting on 21 November 2012
Amendment approved by 169th Administrative Meeting on 18 September 2013

1. National Cheng Kung University (hereinafter the “University”) has established the Human Research Compliance committee (hereinafter the “Committee”) and these Guidelines in accordance with Article 3 of the Provisional Regulations of Governance Framework for Human Research Ethics of the University.
2. The Committee has the following missions:
 - (1) Onsite visit and investigation as to whether human research projects are executed in accordance with the approved details of ethics review.
 - (2) Process complaints and investigation cases from research participants.
 - (3) Process appeal cases of human research projects.
 - (4) Assistance with evaluations of performance results of Human Research Ethics Governance Framework.
 - (5) Assistance with appraisal and improvement of quality and efficiency of review by relevant research ethics review committee.
 - (6) Assistance with preparing the draft of specific execution proposals of research ethics regulations and educational training matters.
 - (7) Other matters related to the interests of human research projects.
3. The members of the Committee shall be researchers from inside or outside the University who are familiar with the implementation ideas of Human Research Ethics Governance Framework or who have served as members of human research ethics committees. The number of members from outside the University and the number of members of each gender shall represent at least 1/3 of all members. The terms of members are 2 years and may be renewed upon expiry. The same member may serve again if re-hired.
4. The Committee has 3 to 5 members, one of the members shall be the Chairman. The Director of the Research Center of Humanities and Social Sciences shall recommend the President of the University to hire the candidate of the Chairman from among full-time teachers of the University who meet the requirements under the previous article. The other members shall be nominated by the Chairman and hired by the President of the University.
5. The Committee may conduct onsite visits to human research projects that have been approved and under execution. The visits are divided into the following:
 - (1) Active visits: Depending on the level of risk in research participation, relevant research projects are regularly and randomly selected on a proportional basis to conduct onsite visits.
 - (2) Passive visits: Onsite visits to relevant research projects pursuant to the request by the Research Ethics Committee, the Research Center for Humanities and Social Sciences, the principal investigators and research teams, the project execution institutions, the project funding entities or the government authority in charge of subject industry of the project execution institutions.

6. As requested by the Research Ethics Committee, the Committee may conduct an investigation on complaint cases about the suspected breach to the interests of research participants. The investigation shall be completed within 2 months and the results of the investigation shall be provided to the Research Ethics Committee for further handling.
7. If a request for reconsideration has been filed with the Research Ethics Committee and the principal investigator still objects to the decision, a written appeal may be filed with the Committee within 2 months. The review procedure for appeal cases shall be separately stipulated.
8. There is no remuneration for members of the Committee. However, members who are not staff of the University may be paid review fee, attendance fee and transportation fee.
9. These Guidelines, including any amendment hereof, are implemented following approval by the Administrative Meeting.