

Guidelines for Establishment and Review of Human Research Ethics Committee of National Cheng Kung University

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1. National Cheng Kung University (hereinafter the “University”) has established these Guidelines in accordance with Article 3 of the Provisional Regulations of Governance Framework for Human Research Ethics of the University which stipulates that more than one human research ethics review committee may be established (hereinafter the “Ethics Committee”, short for HREC) in order to duly execute human research, protect the interest of the research participants and plan, review and follow up on the ethics matters in the performance of the relevant research.
2. The Ethics Committee has the following missions:
 - (1) Establish the scope, details, and guidelines for the review of human research ethics.
 - (2) Establish the basis of review procedure for human research ethics.
 - (3) Review and evaluate the reasonableness, feasibility and regular follow-up of human research ethics.
 - (4) Review ethics and legal matters related to the interest of the research participants.
 - (5) Other relevant matters involving the interest of research participants.The above matters shall be determined by joint meetings regularly organized by the chair attended by the majority of all members of all the Ethics Committees.
3. According to the level of research ethics involved in the projects submitted for review, the Ethics Committee divides the cases into three types - cases exempt from ethics review (which is presumed to be in accordance with the ethics) cases for expedited review and full-committee review. The review standards and procedures shall be separately stipulated.
4. To perform reviews, the respective Ethics Committees shall have 7 to 21 members, as well as several experts to perform written reviews (hereinafter “written review experts”).
5. The Ethics Committee shall have one Chair, and the each Ethics Committees shall have 1 to 2 Deputy Chair. The President of the University shall hire the Chair from full-time teachers who have served as a member of the Ethics Committee of the University for one year or longer, who have been certified with professional qualifications by international research ethics organizations or who have academic or practical experience in research ethics. The other members and written review experts shall be recommended by the Chair and hired by the President of the University.

6. Each Ethics Committee shall include legal experts, righteous gentlemen in the society or representatives of research interest related organizations. At least 1/2 of the members shall possess a professional academic background in human research and at least 2/5 shall not be employed in this University. Furthermore, each gender shall represent at least 1/3 of all members of the respective Ethics Committees.
7. The members and Written Review Experts of each Ethics Committee shall serve terms of 2 years. The term may be renewed upon expiry. However, the number of members that are re-appointed to different positions each time shall not exceed half of the total number of members in the committee in principle.
8. The University shall establish and announce clear hiring requirements about the Ethics Committee members, including selection and hiring qualifications and professional credentials, etc. Upon hiring, members of the Ethics Committee shall sign confidentiality agreements and accept training. Their names, occupations, expertise, and relationships with the University shall be announced.
9. Any member of the Ethics Committee with any of the below conditions shall be dismissed:
 - (1) Absences from attendance for 3 or more meetings, or the absent times over 1/3 or more of the required meetings without justification.
 - (2) For reasons attributable to the member that causes failure to timely review cases for 3 or more times.
 - (3) Breach of confidentiality or interest recusal rules.
10. Each Ethics Committee shall hold review meetings regularly and extraordinary review meetings may be held as required. The review meetings shall be convened and chaired by the chair. If the chair cannot attend the meeting due to any reason, the chair shall appoint one deputy chair to act on his/her behalf. Review meetings shall be attended by the majority of all members of the relevant Ethics Committee. The attending members shall include at least one member outside the organization without the background in biomedical science. No meeting shall proceed if all attending members are of the same gender.
11. In holding review meetings, each Ethics Committee may invite the principal investigators of the projects submitted for review, representatives of institutions or organizations, experts or scholars as required sitting in meetings and providing explanations or comments.

The researchers and graduate students may sit in meetings as observers after approval by the chair and after signing confidentiality and interest recusal letters.
12. Resolutions of review meetings of each Ethics Committee shall be approved by the majority of anonymous votes which cast by members of the relevant Ethics Committee attending the meeting. The positive and negative comments and the results of the voting shall be specified in the meeting records.
13. Under the condition of dedication to the promotion of research ethics, the Ethics Committee shall conduct the review and continued follow-up on whether the projects submitted for review are consistent with the below requirements of research ethics:
 - (1) Acknowledgement of each individual's value of life and dignity. Equal care and respect for all interested parties of the research.

- (2) Respect for the participating intentions of the research participants and their autonomy in the process of the research, without any force, threat, manipulation, malicious cheating or provision of undue enticement.
 - (3) Voluntary disclosure to the research participants as to whether there is a conflict of interest with principal investigator of the research project and the research team.
 - (4) In consistency with the purpose of knowledge exploration in each research field and under professional training, give priority consideration to the concerns for the welfare of the research participants and avoid harm to the research participants to the maximum extent possible.
 - (5) Respect the privacy of the research participants and avoid disclosure of personal information.
 - (6) With the objective of pursuing good faith in academic research and obtaining the trust from the research participants and the general public, the design and execution of the research shall be in accordance with academic ethics and integrity norms and related professional ethics guidelines.
 - (7) The research results shall not create discrimination or stigma for the research participants and their community.
14. 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 project submitted for review with proper explanation. The review results shall be provided to the principal investigator in writing.
- If the principal investigator of the project submitted for review objects to the review results, he/she may submit specific grounds to seek reconsideration by the original Ethics Committee. No more than one reconsideration will be conducted. If the objection continues against the results of reconsideration, an appeal may be filed with the Human Research Compliance Committee of the University.
15. Members of the Ethics Committee shall exercise their review duties in an independent manner without any intervention.
16. Projects approved by the Ethics Committee following review shall be subject to continuous follow-up review from the start of their execution until the full completion of the projects, in order to help principal investigator of the project ensure that the project execution is consistent with research ethics norms.
17. There is no remuneration for members of the Ethics Committee and the Written Review Experts. Members and Written Review Experts from outside the University may receive review fees, attendance fees and transportation fees. Members and Written Review Experts from inside the University may receive review fees and attendance fees.
- An attendance fee of NT\$2,000 or less may be paid to members attending review meetings each time. Review fee of NT\$2,000 or less may be paid for written review for each case. However, the review fee may be adjusted depending on the level of complexity of the case and shall not exceed a maximum of NT\$4,000.
- The funds required under the previous two paragraphs shall be paid out of self-generated income. In case of a change in the funding item or amount, the

further submission shall be made to the School Affairs Fund Management Committee for review and approval.

18. The Ethics Committee may have one Executive Secretary, who is responsible for the Chair's requests and who handles daily affairs. There may be several staff under the direction and supervision of the Secretary to handle affairs within the Committee.
19. These Guidelines, including any amendment hereto, are implemented following approval by the Administrative Meeting.