# Yuan Ze University Regulations on Research Project Ethical Review Procedures

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| Mar 19, 2012 | Adopted at the 11th Administrative Council Meeting, Academic Year 2011 |
| Apr 2, 2014 | Revised and adopted at the 18th Administrative Council Meeting, Academic Year 2013 |
| May 27, 2015 | Revised and adopted at the 22nd Administrative Council Meeting, Academic Year 2014 |
| Aug 3, 2022 | Revised and adopted at the 1st Administrative Council Meeting, Academic Year 2022 |

Article 1 These regulations are specifically established in accordance with the trial program for ethical review of special research projects by the National Science and Technology Council (hereinafter referred to as the NSTC) and relevant laws such as the 'Human Research Act' by the Ministry of Health and Welfare (hereinafter referred to as the MOHW).

Article 2 For studies involving human subjects, genetic recombination or transgenic experiments with animals or plants, researchers are required to proactively submit an ethical review application to uphold research ethics and protect the rights of research participants.

Experimental projects are categorized into the following three types:

1. The first category: refers to research projects that involve using human specimens or personal information related to biological behaviors, physiology, psychology, genetics, medicine, etc., for the application of new medical technologies, new pharmaceuticals, new food additives, or new medical equipment on the human body.
2. The second category encompasses projects that use human specimens of research subjects, personal data, and other personally identifiable information for research in the fields of humanities, social sciences, behavioral sciences, or engineering.
3. The third category includes research outside the scope of the first two categories but involves experiments related to genetic recombination, transgenic processes, or experiments with animals or plants.

Article 3 Qualifications of the Principal Investigator

1. Clinical Trials of New Drugs and Technologies: The principal investigator must hold a qualification as a practicing physician and have undergone relevant training courses, meeting the stipulated criteria.
2. Other Research: For research other than clinical trials, the principal investigator should be a full-time faculty member at the lecturer level or above at this university, having participated in relevant training courses and meeting the specified criteria.

Article 4 Application Process:

The principal investigator prepares the necessary documents according to the regulations of the reviewing body and submits the application to the reviewing body. The Research and Development Office coordinates with the reviewing body to handle procedures such as issuing official correspondence or acknowledging receipt of documents, in accordance with the regulations of the reviewing body.

Article 5 For projects requiring submission to research ethics review, the principal investigator may commission the following organizations, depending on the project category, to be responsible for the review of the relevant application. If approval documents cannot be submitted at the time of application, proof of submission for review must be provided, and the approved documents must be completed within four months for the convenience of the review.

1. Category 1: Projects submitted for review by the Ministry of Health and Welfare and reviewed by an authorized institution within the validity period.
2. Category 2: Projects submitted for review by the Administrative Center for the Protection of Research Participants in Northern Taiwan, or other institutions recognized by the National Science Council and within the validity period.
3. Category 3: Projects submitted for review by the school's working group to which the project belongs.

The external review fees are to be paid from the project budget for the year, as specified by the National Science Council. If the principal investigator does not have any project funds available to cover these costs for the year, they may apply to the Research and Development Office for review fee assistance. The principle is to subsidize one review case per person per academic year, and the Research and Development Office will consider providing assistance based on the balance of the current year's budget for supporting faculty research.

Article 6 When a special research project is recognized by the reviewing institution as one involving human research falling into the following categories, it is presumed to comply with research ethics, and subsequent review procedures may be exempted:

1. Conducting non-anonymous observational research in public settings, with no information collected capable of identifying specific individuals.
2. Data or specimens used in non-genetic research have been lawfully collected and stored before the start of the study. Although not anonymized, with the consent of the parties involved, the data or specimens have been processed by a neutral third party and provided for research use in a way that prevents the identification of specific individuals.
3. Personal information used in the research is information that has been lawfully publicly disclosed, and the purpose of the research use is not inconsistent with the purpose of the public disclosure of the information.

Article 7 Format for 'Participant Informed Consent Form

Researchers may design an informed consent form that fulfills the obligation to inform and obtain consent from research participants based on the specific research context. The content of the Participant Informed Consent Form should sufficiently achieve the purpose of ensuring that research participants are well-informed and provide their consent willingly.

Article 8 Revision of Project Proposal

1. When revisions to the project proposal are necessary, the principal investigator should, in accordance with the regulations of the original reviewing institution, prepare relevant documents and submit an application to the original reviewing institution.
2. If the project proposal previously reviewed has been revised without reporting to the original reviewing institution, it will be treated as a new case.
3. Only after receiving the 'Approval of Amendment Certificate' from the reviewing institution and sending it to the National Science Council or the Ministry of Health and Welfare for approval, can the human trial for the proposed amendments proceed.

Article 9 After the experimental plan is approved, it is delivered to the principal investigator for implementation. During the implementation period, there is an obligation to submit reports promptly upon the request of the reviewing institution or the Ministry of Health and Welfare. Depending on the progress of the project, at least one interim report should be submitted during the first half of the project period. If the project duration exceeds one year, reports should be submitted annually. Upon completion or withdrawal of the project, a closing report must be submitted for review by the original reviewing institution. For Category 1 projects, after approval, it is submitted to the Ministry of Health and Welfare for record. The reports should be in writing, and if necessary, the principal investigator may be requested to present an explanation. If the reviewing institution deems there are safety concerns, the trial may be suspended.

Article 10 Closure

1. Upon completion or expiration of the project, the principal investigator must, in accordance with the regulations of the reviewing institution, prepare relevant reports and documents for submission to the reviewing institution for closure review.
2. After receiving the closure notice from the reviewing institution, the closure procedures will be carried out according to the regulations, either through the National Science Council or the Ministry of Health and Welfare. Failure to complete the closure procedures will prohibit the initiation of other research projects

Article 11 If there are matters not covered in these operating regulations, they shall be governed by the trial program for ethical review of special research projects by the National Science Council and the Human Research Act, as well as related regulations and provisions of the Ministry of Health and Welfare.

Article 12 These regulations, as well as all subsequent revisions therewith, shall be duly adopted by the Administrative Council prior to implementation.