

Enforcement Rules of Application Processes of Institutional Review Boards (IRBs) of National Yang Ming Chiao Tung University

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- Article 1 The Enforcement Rules of Application Processes of Institutional Review Boards (IRBs) of National Yang Ming Chiao Tung University (hereinafter referred to as the “Enforcement Rules”) are established in accordance with the Human Subjects Research Act.
- Article 2 Any personnel of NYCU who wish to conduct human research or human subjects research shall apply with the Institutional Review Boards (IRBs) of NYCU for review, in order to protect the subjects’ rights.
- Article 3 The terms used herein are defined as following:
human subjects research: refers to research involving obtaining, investigating, analyzing, or using human specimens or an individual person’s biological behavior, physiological, psychological, genetic, or medical information.
Human research: refers to the systematic or academic knowledge exploration activity targeting “human beings” (single person or group) and in the manners including observation, intervention or interaction, or using the personal data of which the identifying link has not been removed with the personal consent.
- Article 4 The IRB research review is categorized into the following three types:
Exempt review: Applicable to the human subjects research which may be exempted from the IRB review according to the public notice made by Ministry of Health and Welfare.
Expedited review: Applicable to the human subjects research which may apply the expedited review according to the public notice made by Ministry of Health and Welfare.
Full-committee review: The projects which request the full-committee review, excluding the human trial referred to in Article 8 of the Medical Care Act.
The Principal Investigator shall file the application with the IRBs in accordance with the Enforcement Rules. The IRBs will render the final decision subject to the risk level.
- Article 5 Qualified applicants: Full-time/part-time faculty of NYCU, and full-time medical and administrative staff of the hospital affiliated to NYCU or hospital under the cooperative project of NYCU who have completed any human research-related training.
- Article 6 When filing the application, the applicant shall pay the review fees to the Cashier’s Division based on the payment notice. For the fee rates, please refer to Schedule 1. If the research is self-funded without fund provided by any institution or manufacturer but subject to approval of the REC Director, the IRBs may reject the new application if the review fees are not paid in full without justified causes, provided that the review fees may be credited/exempted in the case of full-committee review cases.
For the review fee payment, please refer to Schedule 2. The expenses for any necessary stationery, paper, reproduction, cups, meeting meals and other miscellaneous items shall be paid on a reimbursement basis.
- Article 7 Application documents:
1. Application form for review on human subjects research
 2. Expedited review checklist
 3. Informed Consent Form of a research subject (not required, in the case of the application for exemption from, or change in, the informed consent)
 4. Letter of undertaking by the research team
 5. The protocol shall consist of budget statement, Principal Investigator’s resume, main research HR form and related review data.
 6. English title and Chinese abstract of the protocol

7. The Principal Investigator and Co- (Sub-) Investigator shall submit a photocopy of the certificate showing attendance to the human research and ethics training courses for 6 hours within 2 years, unless the foreign researchers are not those obtaining the informed consent form physically.

Article 8 The applications shall be identified by the REC Director and Executive Secretary subject to the risk level, and then related operating procedures may be carried out.

Exempt review: For the case satisfying the exempt review requirements, an “exempt review certificate” will be awarded. If the case is held failing to satisfy the exempt review requirements, the Principal Investigator shall file the application for expedited review or full-committee review instead.

Expedited review: For the case satisfying the expedited review requirements, the Executive Secretary shall appoint 2 members to conduct the preliminary review, and send experts to conduct the review, if necessary. The Principal Investigator shall give response within 10 working days upon receipt of the preliminary review opinions. The Principal Investigator’s failure to do so shall constitute his/her waiver.

Full-committee review: For the cases other than those referred to in the preceding two paragraphs and the human trial referred to in Article 8 of the Medical Care Act, the Executive Secretary shall appoint 2 members to conduct the preliminary review, and send experts to conduct the review, if necessary. The Principal Investigator shall give response within 20 working days upon receipt of the preliminary review opinions. If the Principal Investigator fails to do so within specific time limit, he/she shall notify the case handler in writing, and may apply for an extension no more than twice. The Principal Investigator’s failure to do so shall constitute his/her waiver.

Article 9 After the research project is approved, the Principal Investigator shall be obligated to submit reports from time to time during the conduct of the research, upon the IRBs’ request. In the case of any safety concern, the IRB may suspend the research. Upon completion of the research, the Principal Investigator shall submit the case closure report in writing, and may be invited to attend a meeting to provide a statement, if necessary.

Article 10 Where it is necessary to extend the term of the research project, the Principal Investigator shall submit the complete application documents for the extension within six weeks prior to the time limit in which the project is approved to be executed. Each extension requested shall be no more than one year.

Article 11 Where it is necessary to change the research project, the Principal Investigator shall prepare relevant information and submit the same to the IRBs for review.

Article 12 The Enforcement Rules shall be promulgated and enforced upon approval of the IRBs. The same shall apply where the Enforcement Rules are amended.

Schedule 1

Review Fee Rates of Institutional Review Boards (IRBs) of National Yang Ming Chiao Tung University

Case category	Staff from NYCU	Staff outside NYCU
Exempt review	NT\$2,000 (NT\$600 upon the credit/exemption)	NT\$2,500
Expedited review	NT\$5,000 (NT\$1,500 upon the credit/exemption)	NT\$16,000
Full-committee review	NT\$5,000	NT\$18,000
Change review	No charge	NT\$2,500

Schedule 2

Review Fee Payment Standards of Institutional Review Boards (IRBs) of National Yang Ming Chiao Tung University

Category		Fees
New application review	Case assignment fees	NT\$400/case
	Exempt review	NT\$400/case
	Expedited review	NT\$1,500/case
	Full-committee review	NT\$1,500/case
Subsequent review	Extension review	NT\$500/case
	Change review	NT\$500/case
	Case closure review	NT\$500/case
Attendance fees for members outside NYCU		NT\$2,000/count