

# Regulations Governing Establishment of Institutional Review Boards (IRBs) of National Yang Ming Chiao Tung University

Approved at the 2nd Administrative Affairs Meeting of NYCU for Academic Year 2020 on February 24, 2021  
Amended and approved at the 1st Special Administrative Affairs Meeting of NYCU for Academic Year 2021 on July 20, 2022

## Article 1 Purpose

In order to regulate the right protection of human subjects research and human research subjects and execute the human-oriented research, including research involving obtaining, investigating, analyzing, or using human specimens or an individual person's biological behavior, physiological, psychological, genetic or medical information in line with the related laws and ethical requirements, NYCU hereby establishes the Institutional Review Board (hereinafter referred to as the "IRBs").

NYCU establishes two institutional review boards:

- I. 國立陽明交通大學人體研究倫理審查委員會 A, English name: Institutional Review Board A (IRB-A) of National Yang Ming Chiao Tung University (hereinafter referred to as "IRB-A")
- II. 國立陽明交通大學人體研究倫理審查委員會 B, English name: Institutional Review Board A (IRB-B) of National Yang Ming Chiao Tung University (hereinafter referred to as "IRB-B")

## Article 2 Mission and Responsibility

- I. Establish the research ethics review policy, regulations and scope related to human research and human subjects research.
- II. Determine the contents and review highlights to be included in the human research and human subjects research protocol, which, subject to the risk level, are divided into the full-committee review, expedited review and exempt review.
- III. Review and audit the interest and right of the subjects in human subjects research and human research projects, and ethics and legality of the research protocols, and follow up the management status and report the same to NYCU regularly, and assist in any investigation, if necessary.
- IV. Monitor the corrective actions against any violations of any matters related to human research ethics, and terminate the human subjects research and human research if necessary.
- V. Other matters related to the human subjects research and human research.

## Article 3 Independence of IRBs

In order to exercise the right to review independently, the IRBs are free from any undue influence posed by NYCU, Principal Investigator and Contract Research Organization (CRO). They shall also follow up the management status of the research project and report the same to NYCU regularly, and assist in any investigation if necessary.

## Article 4 Organization of IRBs

Each of the IRB-A and IRB-B has 7–21 members, and appoints one chairman and one vice chairman. The chairman shall be appointed by the President of NYCU, while the other members are recommended by the chairman and selected and appointed by the President of NYCU. The vice chairman may be elected among the members. The chairman may appoint 1–3 persons out of the other members to serve as the executive secretary to help the chairman take charge of the overall planning about the IRB.

Each IRB's members shall comply with the following background requirements:

- I. Each IRB's members shall consist of persons with the background in biomedical science or humanities and social science. At least one of them shall have background in laws, and also at least one of them is a disinterested community member or representative of any related private group.
- II. The number of each IRB's members outside NYCU shall attain two-fifths of the whole members, and no gender shall constitute less than one-third.
- III. The member shall possess the certificates related to subjects' protection, human research ethics or medical ethics seminars and conferences.

The members shall hold the term of office for two years, and may be re-engaged for successive terms, provided that the number of re-appointed members shall be no more than one-half of the total members.

Vacancies of the member, if any, shall be filled by others appointed by the President of NYCU upon the IRB's request separately.

#### Article 5 Qualifications of the chairman

The chairman shall meet any of the following qualifications:

- I. Has been served as a member of the institutional review board reviewed and approved by the competent central authority for each industry concerned, or the institutional review board promoted by related ministries/departments for more than two years.
- II. Has passed the qualification certification for the profession in research ethics by any international research ethics organization.
- III. Has academic or practical experience in research ethics.

The post of chairman shall be assumed by the management in charge of research operations directly, other than Dean of Research and Development or Deputy Dean of Research and Development of NYCU.

#### Article 6 IRBs Meeting

Subject to the need for review of cases, the IRB may convene a meeting regularly, and a special meeting whenever necessary.

An IRB meeting may be convened only if a majority of the members attend it. At least one of the present members shall have a background in biomedical science or humanities and social science, and at least one of them who is a non-professional disinterested community member with a background in law. A resolution may be made only upon approval of a majority of the present members. No meeting shall be called to order if all of the present members are of a single gender.

#### Article 7 Dismissal and replacement for vacancy of the member

Where a member meets any of the following circumstances, NYCU may notify him/her in writing to discharge him/her from the job duty per resolution of the IRB meeting.

- I. Absent from meetings for more than three times consecutively without justified cases or for more than one-half of the required frequency of attendance cumulatively during his/her term of office.
- II. The meeting is postponed more three times cumulatively due to the cases reviewed by him/her with the causes attributed to him/her.
- III. Materially violating the principles of recusal for conflict of interest.

Where a member position becomes vacant with causes, the current Chairman shall search and inquire the member candidate and the IRB shall disclose any qualified member candidates recommended by various schools of NYCU.

According to Article 4 of the Regulations for Establishment of Institutional Review Board, upon expiration of any member's term of office, the President of NYCU will be proposed to appoint a new chairman and select the name list of the new IRB members, and convene the IRB meeting to have the new members elect one vice

chairman among them. The chairman may designate 1–3 persons from the members to serve as the Executive Secretary.

Article 8 Source of budget of the IRBs, and operations of the budget  
NYCU shall ensure that the IRBs have sufficient and stable operating fund. The sources of such fund include the fixed fund contributed by NYCU, subsidy from government ministries/departments, or other self-financing.

NYCU also establishes the Research Ethics Center for Human Subject Protection (REC) separately, and appoints full-time and part-time staff to handle the overall planning about the IRBs' administrative affairs, help the IRBs' audit and monitoring over the execution of the human subject research and human research projects, and handle the adoption and coordination mechanism for ethical review standards among various institutional review boards.

Article 9 In order to perform the duties required herein, a standard operating procedure shall be established separately, and implemented upon approval and promulgation by the IRBs.

Anything not mentioned herein shall be governed by other applicable laws or the competent authority's requirements.

Article 10 The Regulations shall be promulgated and enforced upon approval of the Administrative Affairs Meeting of NYCU. The same shall apply where the Regulations are amended.