

# **National Yang Ming Chiao Tung University Regulations Governing Establishment of Research Ethics Center for Human Subject Protection (REC)**

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 help the operation of “Institutional Review Boards of National Yang Ming Chiao Tung University” (hereinafter referred to as the “IRBs”), protect the research subjects’ interest and right, and execute the mission and related administrative operations assigned by the IRBs, the “Research Ethics Center for Human Subject Protection (“REC”) of National Yang Ming Chiao Tung University” is established in accordance with the “MOE Directions for Audits by Research Ethics Committees.”

## **Article 2 Mission and Responsibility of the REC**

- I. Execute various administrative affairs about the IRBs;
- II. Help the operations of IRBs and enactment/revision of various laws and regulations;
- III. Help the IRBs supervise and audit ethics cases, and also help the compilation of related documents and reports;
- IV. Plan and execute the human research ethics training courses, conferences, forums or related activities;
- V. In response to business needs and important issues, invite personnel from related units inside/outside NYCU to convene the communication meeting to facilitate establishment of the research ethics policies or promotion and execution of related business;
- VI. Execute the tasks assigned by the IRBs.
- VII. In order to perform the duties required herein, a standard operating procedure shall be established separately.

## **Article 3 Organizational Division of Job and Staffing**

The REC shall appoint one Director and at least one Deputy Director, and several administrative staff. The Director shall be appointed by the President, while the Deputy Director and administrative staff shall be recruited by the Director. The Director shall recommend the full-time faculty of NYCU as the candidate for the Deputy Director, who shall also be appointed subject to approval of the President.

Article 4 Qualifications of the administrative staff

The REC's administrative staff may be selected from the units inside/outside NYCU. The staff shall hold the academic background for university degree or above and the experience in plan management, and have undertaken human research ethics-related administrative affairs, or attended the human research ethics training courses or related conferences for more than 12 hours within 1 year.

Article 5 The Director's authority and power

- I. Oversee the REC's operations;
- II. Convene the REC meeting regularly to discuss and execute the missions assigned by the IRBs;
- III. Help take charge of and supervise the REC's administrative work;
- IV. Allowed to attend the IRBs meetings.

Article 6 The Deputy Director's authority and power

- I. Help the Director supervise the business his immediate staff are committed to promoting;
- II. Serve as the Director's functional substitute;
- III. Responsible for the special mission assigned by the Director.

Article 7 Functions of the administrative staff

The REC's administrative business requires the special operations including the plan (research project) management, activity planning and advisory services, subject to the nature of work. Various special operations may be promoted by taskforces. Various forces may support each other in response to important meetings or activities. The related functions are stated as following:

- I. Plan management: Application, submission, continuing review, authorization, amendment, and SAE reporting, with respect to study projects; follow-up, audit, visit, interim (final) report management and establishment of related SOPs, with respect to the protocols under execution;
- II. Activity planning: Collection of related important cases, education & training, planning and organization of conferences, forums or related activities, network maintenance, and establishment of related SOPs, etc.;
- III. Advisory services: Business consulting services, acceptance of complaints, inquiry on human research ethics-related laws & regulations, organization of cross-functional communication meetings, and establishment of related SOPs, etc.;

Article 8 Right and obligation of the REC personnel

- I. Required to attend important subject protection or human research ethics meetings or attend related educational training programs at home or abroad from time to time, for no less than 12 hours per year.
- II. All of the personnel shall execute the agreement on recusal for conflict of interest and confidentiality.
- III. The administrative staff shall accept the evaluation each year. Those who are found with poor performance or unwilling to respond to the evaluation may be dismissed, or succeeded by the personnel recommended by related units of NYCU separately.

Article 9 The REC Director shall hold the term of office for two years, which may be renewed upon expiration. Whether the administrative staff's term of office may be renewed shall be decided based on their performance each year.

Article 10 NYCU provides the REC with independent premises where the REC personnel perform job duties and store documents and files. The funds for the REC's operations are sourced from the revenue from government subsidies, organization of conferences and educational training programs, or other self-raised expenditures.

Article 11 Any matters not covered herein shall be resolved in accordance with the relevant SOPs of the IRBs and REC, and also the competent authority's laws and other related laws and regulations.

Article 12 The Regulations shall be promulgated and enforced upon approval of the Administrative Affairs Meeting. The same shall apply where the Regulations are amended.