

National Chengchi University Guidelines for the Human Research Ethics Governance framework

Approved by the 649th Administrative Meeting on November 6, 2013

Revisions of Article 2 and 5 approved at the 664th Administrative Meeting on March 9, 2016

Revisions of Article 7 approved at the 695th Administrative Meeting on October 5, 2022

Revisions of Article 2 approved at the 700th Administrative Meeting on October 4, 2023

- Article 1 To properly conduct human research and protect the rights and interests of research participants, National Chengchi University (hereinafter "the University") has established these guidelines.
- Article 2 Human research refers to individuals or groups of people as research subjects or participants. A research activity can be a systematic investigation or knowledge discovery activity of any academic discipline, that entails research methods such as observation, intervention, interaction, or non-consensual use of participants's data whether identity cues are delinked or not. This excludes human trial research as defined in Article 8 of the Medical Care Act.
- Human research involving 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.
- Article 3 To formulate policies for the protection of research participants, promote education, and plan audits, the University establishes the Human Research Ethics Advisory Committee (hereinafter "the Advisory Committee"). The guidelines for the Advisory Committee are defined separately.
- Article 4 To set review operation standards, conduct research ethics reviews, and manage subsequent follow-ups, the University establishes the Human Research Ethics Review Committee (hereinafter "the Review Committee"). The guidelines for the Review Committee are defined separately.
- The Review Committee members must independently conduct project reviews without influence from the project's affiliated unit, principal investigator, or sponsor.
- Article 5 To execute the resolutions of the Advisory Committee and assist the Review Committee in conducting administrative business related to research ethics reviews, the University establishes the Research Ethics Administrative Office (hereinafter "the Administrative Office") under the Office of Research and Development. The Administrative Office must report annually on the management and follow-up of human subjects research conducted by the University's faculty to the Research and Development Meeting and assist with further investigations as necessary.
- Article 6 The Administrative Office shall have one Director responsible for promoting the office's operations. The Director shall be recommended by the Vice President for Research and Development from among relevant section chief of the Office of Research and Development and appointed by the President. The term of Director is two years, with the possibility of re-appointed. The Administrative Office shall also have dedicated administrative staff responsible for executing tasks related to the Review Committee and the

Administrative Office, who must undergo educational training.

Article 7 The funding required for the Administrative Office shall be covered by government subsidies or the University's self-generated income.

Article 8 Guidelines not covered in this document shall be governed by other relevant laws and regulations as necessary.

Article 9 These guidelines shall be implemented after approval by the administrative meeting of the University and shall be revised in the same manner hereafter.