

Guidelines for Establishing the Biosafety Committee at Chung Yuan Christian University

Approved in the 848th Administrative Meeting on May 1, 2008
Amended to revise the committee's name and corresponding text as per
Letter No. 0990000878 dated March 30, 2010
Amended as per Letter No. 1030000643 dated March 5, 2014
Amended as per Letter No. 1050002657 dated August 25, 2016
Amended in the 963rd Administrative Meeting on August 16, 2018
Amended in the 998th Administrative Meeting on March 3, 2022
Amended as per Letter No. 1110002691 dated August 3, 2022

Article 1 To ensure the safe management and operation of biological experiments, the university establishes a Biosafety Committee (hereinafter referred to as "the Committee") in accordance with the "Guidelines for Genetic Recombination Experiments" set by the National Science and Technology Council and the requirements of the "Regulations on the Management of Infectious Biological Materials" issued by the Ministry of Health and Welfare's Centers for Disease Control.

Article 2 The Committee shall consist of 5 to 9 members. The Chairperson shall be the President of the university or a Vice President designated by the President. The Biosafety Officer shall serve as an ex-officio member, while other members are appointed by the President from among faculty experts in microbiology and cell culture, virology, animal and plant studies, and bioethics and law. The term of appointment is one year.
The Biosafety Officer must have at least three years of experience in laboratory biosafety and biosecurity.

Article 3 The duties of the Biosafety Officer are as follows:

1. Serve as the liaison for external matters related to the university's biosafety and biosecurity.
2. Provide consultation on biosafety and biosecurity for laboratories and storage facilities.
3. Review applications for the possession, use, import/export, storage, or disposal of risk group 2 to risk group 4 pathogens and biological toxins.
4. Supervise biosafety and biosecurity training for laboratory and storage facility personnel.
5. Conduct internal audits of laboratory and storage facility biosafety and biosecurity annually.
6. Oversee competency evaluations for high-containment laboratory personnel and the operation of biosafety risk management systems.
7. Supervise emergency drills conducted by laboratories and storage facilities.
8. Oversee cleaning and disinfection operations before equipment maintenance or repairs.
9. Supervise decontamination in case of spills or accidents involving infectious biological materials.
10. Oversee the disposal of laboratory and storage facility waste.
11. Investigate biosafety and biosecurity incidents or anomalies, report findings and improvement recommendations to the Committee.

Article 4 The responsibilities of the Committee are as follows:

1. Review research projects involving genetic recombination experiments proposed by university faculty to ensure compliance with the "Guidelines for Genetic Recombination Experiments" issued by the National Science and Technology Council.
2. Establish policies and regulations for laboratory biosafety and biosecurity management.
3. Evaluate and supervise applications for the possession, storage, use, disposal, or import/export of risk group 2 or higher pathogens and biological toxins.
4. Evaluate and supervise the biosafety levels of laboratories using risk group 2 or higher pathogens and biological toxins.
5. Review emergency response plans for laboratories and storage facilities.
6. Evaluate plans for the construction, renovation, commissioning, or decommissioning of laboratories and storage facilities.
7. Address disputes related to biosafety and biosecurity in laboratories and storage facilities.
8. Develop biosafety training and health monitoring mechanisms for related personnel (including Committee members, project leaders, laboratory staff, and biosafety officers).
9. Audit and oversee other matters concerning the biosafety and biosecurity of infectious biological materials, laboratories, and storage facilities.
10. Supervise annual internal audits of laboratory biosafety and improvement of identified deficiencies.
11. Manage necessary actions, investigations, and reporting in the event of an accident.

Article 5 The Committee shall convene meetings once per semester, with additional meetings held as needed.

Article 6 Committee meetings require the attendance of more than half of its members to proceed. Resolutions must be approved by more than half of the attending members. Relevant experts and scholars may be invited to attend as advisors, and project leaders may be requested to provide reports when necessary.

Article 7 These guidelines shall take effect upon approval by the Administrative Meeting and promulgation by the President. Amendments shall follow the same procedure.