NATIONAL TAIWAN UNIVERSITY
Regulations for the Management of Infectious Biological Materials

November 23, 2006	Amended and passed by the Biosafety Management Committee
January 10, 2007	Amended and passed by the Environmental Protection and Occupational Safety and Health (EHS) Committee
February 27, 2007	Amended and passed by the 2,469th Administrative Meeting
February 17, 2014	Passed by the 2,799th Administrative Meeting
November 18, 2014	Amended and passed by the 2,835th Administrative Meeting
January 15, 2019	Passed by the 3,027th Administrative Meeting

Article 1 National Taiwan University (NTU or "the University") formulates the NTU *Regulations for the Management of Infectious Biological Materials* ("the Regulations") to effectively manage infectious biological materials, prevent environmental pollution, and safeguard the wellbeing of its faculty, staff, and students.

Article 2 Definitions:

1. Competent academic program/college/unit: A department, graduate institute, center, division, or college (or a subordinate unit of the above) which handles infectious biological materials at the University
2. Laboratory: A laboratory, venue for conducting experiments, or place of a similar nature where infectious biological materials are handled by the competent academic program, college, or unit
3. Laboratory representative: A supervisor, course instructor, or quota-based faculty member appointed by the head of the competent academic program, college, or unit to be in charge of the handling of infectious biological materials in a laboratory
4. Infectious biological materials: Infectious pathogens and their derivatives, and other materials that are confirmed to contain such pathogens and their derivatives

Article 3 The Environmental Protection and Occupational Safety and Health (EHS) Center shall be responsible for oversight in accordance with the provisions herein and shall be charged with the following tasks:

1. Provision of guidance to competent academic programs, colleges, and units on matters related to the Regulations
2. Handling of applications for the procurement, destruction, depletion, storage, distribution, and transfer of biological materials for all laboratories
3. Organization of biosafety training sessions
4. Assistance in the handling and resolution of biohazard incidents

Article 4 Infectious biological materials that are pathogenic microbes shall be classified into four risks groups (RG1 to RG4) based on their pathogenicity, mode(s) of transmission, host range, and prevention/treatment methods (or lack thereof).

Matters related to the classification, itemization, and quantity control for microbes and biotoxins in each risk group shall be subject to the Ministry of Health and Welfare's *Directives Governing the Management of Infectious Biological Materials*.

Article 5 Newly-hired personnel expected to handle or come into contact with infectious biological materials or gene recombination experiments shall participate in eight hours of biosafety training organized by the University and pass an examination before they may begin work. Said personnel shall participate in four hours of additional biosafety training for each subsequent year spent at the University. Newly-hired personnel of BSL-3 (biosafety level 3) or BSL-4 laboratories shall participate in biosafety training organized by the central supervisory authority.

Article 6 Academic programs, colleges, and units that wish to export/import infectious biomaterials to/from a foreign territory shall submit an application online in accordance with the applicable regulations, obtain the approval of the NTU Biosafety Management Committee ("the Committee"), and wait for the EHS Center to request the supervisory authority's approval before being permitted to do so.

Article 7 The possession, preservation, use, handling, and storage of RG2-RG4 infectious biological materials shall be subject to the following provisions:

1. A biological material manager shall be designated to take charge of managing such materials and taking inventory on a regular basis.
2. Such materials shall be stored in a secure location with access control.
3. A manifest and access log shall be maintained.
4. Inventories (of items and their quantities) of RG2-RG4 microbes and biotoxins shall be taken on a regular basis. The Committee shall be notified immediately upon discovery of any loss of or inconsistency discovered during an inventory audit.

Article 8 When an academic program, college, or unit is to procure, destroy, deplete, deposit, or transfer any RG2-RG4 infectious biological materials, the holder of such materials shall submit an online application to the Committee for approval and complete all government-mandated procedures before doing so.

Article 9 Competent academic programs, colleges, and units which wish to transfer RG2-RG4 infectious biological materials in their possession to another unit shall ensure that the unit to which such materials are being transferred to has submitted proof of the qualifications of their personnel and equipment for the handling of such materials to the Committee for review. If the receiving unit is deemed to lack the professional knowledge or equipment necessary to handle such materials, such that it may potentially result in environmental hazards or threats to the health of plants, human beings, or animals, the transfer application shall be denied.

Article 10 A receiving unit that causes environmental pollution, the contraction of diseases, death, or other accidents as a result of their use of transferred biological materials shall notify the endowing unit immediately and submit

a report to all competent authorities. Any liability arising from said accidents shall be borne solely by the receiving unit.

Article 11 The use of biological materials may not infringe on the intellectual property rights or any other applicable rights owned by third parties. When presenting findings derived from transferred biological materials, the receiving party shall indicate the name of the endowing party; such information shall also be included on patent applications. The receiving party may not transfer received biological materials to another party in any way unless the receiving party has obtained the consent of the original endowing party in writing.

Article 12 Infectious biological materials shall be transported in triple-layer packaging, as mandated by the central supervisory authority. If such materials are to be transported by air, additional packaging requirements stipulated by the competent authority or authorities for the target industry hall apply.

In the event that a leak of infectious biological materials occurs while in transit, the carrier or other related personnel shall notify the sender, make a report in accordance with the Committee's *Procedures for the Handling of Biosafety Accidents (Infections)*, and take necessary containment measures.

Article 13 The biosafety level for each laboratory shall be assigned by the Committee following its review and approval of such, and each laboratory shall then label biohazardous materials and prepare the appropriate emergency response procedures based on its assigned biosafety level.

Article 14 Newly established BSL-3 and BSL-4 laboratories may only begin operations with the approval of the Committee following a review of documents in writing and an on-site inspection, as mandated by the central supervisory authority.

Article 15 Matters related to the standard operating procedures and equipment requirements for laboratories at any biosafety level shall be subject to the *Standard Operating Procedures for the Safe Handling of Biological Materials* formulated by the central supervisory authority.

Article 16 Laboratories at any biosafety level shall ensure that their biosafety cabinets and autoclaves comply with the applicable labor safety regulations, that such equipment is maintained by a professional crew, and that such equipment undergoes regular functional validation by an agency authorized by the central supervisory authority.

Article 17 Records for the handling of infectious biological materials in any risk group shall be retained for at least two years for reference and auditing purposes.

Article 18 Laboratories at any biosafety level which are found to have major deficiencies in their compliance with the provisions stipulated herein shall be required to make necessary improvements by a specified deadline. The Committee may resolve to suspend the operations of any laboratories that fail to do so.

Article 19 If a biosafety incident occurs at a laboratory, the laboratory representative or on-site personnel shall make a report immediately in accordance with the

Committee's *Procedures for the Handling of Biosafety Accidents (Infections)* and take the appropriate response measures as necessary.

Article 20 Matters not addressed herein shall be subject to the applicable regulations of the University and the central supervisory authority.

Article 21 The Regulations shall be passed by the EHS Committee and the Administrative Meeting and then implemented on the date of promulgation.