**高雄醫學大學生物性實驗之管理與實驗室設置規範辦法**

**Kaohsiung Medical University**

**Regulations Governing the Management of Biological Experiments and Establishment of Laboratories**

 100.12.14 100學年度第二次生物實驗安全委員會議通過

December 14, 2011 Passed by the 2nd the Biological Experiment Safety Committee Meeting of the Academic Year 2011

101.01.12 100學年度第六次行政會議通過

January 12, 2012 Passed by the 6th the Administrative Meeting of the Academic Year 2011

101.02.06 高醫環安字第1011100214號函公布

February 06, 2012 Promulgated via the KMU official letter Huan An Tzu No. 1011100214

103.01.15 102學年度第二次生物實驗安全委員會議通過

January 15, 2014 Passed by the 2nd the Biological Experiment Safety Committee Meeting of the Academic Year 2013

103.06.30 102學年度第四次生物實驗安全委員會議通過

June 30, 2014 Passed by the 4th the Biological Experiment Safety Committee Meeting of the Academic Year 2013

103.12.18 103學年度第5次行政會議通過

December 18, 2014 Passed by the 5th the Administrative Meeting of the Academic Year 2014

104.07.06 高醫環安字第1041102163號函公布

July 06, 2015 Promulgated via the KMU official letter Huan An Tzu No. 1041102163

|  |  |
| --- | --- |
| 第一條Article 1 | 高雄醫學大學(以下簡稱本校)為規範及管理生物性實驗，使生物性實驗運作更具效率並合乎環境保護及職業安全衛生，以確保教職員工生之安全，依據衛生福利部疾病管制署「感染性生物材料管理辦法」訂定本辦法。Kaohsiung Medical University (KMU) formulates the Regulations Governing the Management of Biological Experiments and Establishment of Laboratories in accordance with the Regulations Governing Management of Infectious Biological Materials sanctioned by Taiwan Centers for Disease Control, Ministry of Health and Welfare (CDC, MOHW) to regulate and manage biological experiments, so that biological experiments can be carried out more efficiently and in compliance with environmental protection and occupational safety and health standards, and the safety of faculty and staff can be ensured. |
| 第二條Article 2 | 本辦法之適用範圍為本校所有操作生物性實驗材料之實驗場所。These Regulations are applicable to experimental sites of KMU that handle biological test materials. |
| 第三條Article 3 | 本校「生物安全會」(以下簡稱生安會)為生物安全政策及監督之權責單位，職責如下：KMU’s Institutional Biosafety Committee (IBC) is the responsible unit for biosafety policies and supervision, and its duties include:1. 審核第二級以上危險群微生物或生物毒素之持有、保存、使用、處分或輸出入。
2. Review the possession, storage, usage, disposal, or import/export of Risk Group 2 microorganisms or biological toxins or above.
3. 審核使用第二級以上危險群微生物或生物毒素實驗室之生物安全等級。
4. Review the biosafety level of laboratories that use Risk Group 2 microorganisms or biological toxins or above.
5. 審核實驗室之生物安全緊急應變計畫。
6. Review the biosafety emergency response plan for laboratories.
7. 審核實驗室之新建、改建、擴建、啟用或停止運作計畫。
8. Review the plans for new construction, renovation, expansion, commissioning, or decommissioning of laboratories.
9. 審核實驗室之生物安全爭議事項。
10. Review biosafety-related disputes in laboratories.
11. 督導每年辦理實驗室之生物安全內部稽核及缺失改善。
12. Supervise the annual internal biosafety audit of laboratories and the improvement of deficiencies.
13. 督導實驗室人員之生物安全訓練。
14. Supervise the biosafety training of laboratory personnel.
15. 審核及督導其他有關感染性生物材料及實驗室之生物安全管理事項。
16. Review and supervise other biosafety management matters related to infectious biological materials and laboratories.
17. 處理、調查及報告實驗室之生物安全意外事件。
18. Handle, investigate, and report biosafety incidents in laboratories.

「環保暨安全衛生室生物安全組」(以下簡稱生安組)為生物安全管理執行單位，負責執行本校生安會決議之事項。The Biosafety Division of the Office of Environmental Protection, Occupational Safety and Health is the executive unit of biosafety management, responsible for executing the resolutions made in the KMU IBC meetings. |
| 第四條Article 4 | 本校各等級生物性實驗室皆需主動向生安組登記。未主動向生安組登記之實驗室，生安組有權終止其實驗室運作，直至提出登記申請並獲得核准後方可恢復進行實驗。有爭議時提生安會決議。Biological laboratories of all levels in KMU shall proactively register with the Biosafety Division. Laboratories that fail to register will have their operations suspended by the Biosafety Division, and experiments shall not be performed until a registration application is submitted and approved. Any disputes shall be referred to the Biosafety Committee for resolution.生物性實驗室及感染性生物材料之等級依衛生福利部疾病管制署「感染性生物材料管理辦法」第三及四條規定。生安會得對本校生物性實驗室進行等級鑑定並授予等級證明，或輔導使其符合規範。Biological laboratories and infectious biological materials are classified according to Articles 3 and 4 of the Regulations Governing Management of Infectious Biological Materials by CDC, MOHW. IBC may determine the KMU biological laboratory level and issue the level certificate, or provide guidance for compliance with the regulations. |
| 第五條Article 5 | 生物安全第二等級以上實驗室，應於明顯處標示生物安全等級、生物危害標識、實驗室主管、管理人員姓名、聯絡電話及其緊急處理措施。Level 2 biosafety laboratories or above shall display the biosafety level, biohazard labels, names of the laboratory supervisor and manager, contact phone numbers, and emergency response measures at a prominent position. |
| 第六條Article 6 | 第二級以上危險群微生物或生物毒素之保存場所，應辦理下列事項：For storage of Risk Group 2 microorganisms or biological toxins or above, the following shall be done:一、指派專人負責管理。1. Assign a designated person to undertake the management work.

二、設有門禁管制。1. Implement access control.

三、備有保存清單及存取紀錄。1. Maintain a storage inventory and input/output records.

管理人員應負責實驗室登記與等級鑑定、使用人員資格審核、門禁管理、感染性生物材料管理及保全、實驗室自我檢查、配合生安組稽查及緊急應變措施演練、設備維護、感染性廢棄物處理等相關事務。The management is responsible for laboratory registration and level determination, user qualification review, access control, management and safekeeping of infectious biological materials, laboratory self-inspections, cooperation with Biosafety Division for audits and emergency response drills, equipment maintenance, handling of infectious waste, and other related tasks. |
| 第七條Article 7 | 本校生物安全等級二級(以下簡稱BSL-2)以上生物性實驗室由研究資源整合發展中心(以下簡稱研資中心)負責整合、分配與管理，本校之BSL-2以上實驗室皆需先向研資中心登記核備。必要時，研資中心可將校內各BSL-2以上實驗室委託附近教學或研究單位就近專責管理，但研資中心需負監督之責任。Biological laboratories of Biosafety Level 2 (BSL-2) or above in KMU shall be consolidated, allocated, and managed by the Center for Research Resources and Development (CRRD). All BSL-2 laboratories or above in KMU shall register with CRRD and obtain approval in advance. CRRD may commission nearby teaching or research units for the management of BSL-2 laboratories or above in KMU when necessary, but CRRD shall take supervisory responsibility. |
| 第八條Article 8 | 感染性生物材料之操作人員應參加相關生物安全教育訓練及測試合格後始得進行實驗。實驗室新進人員應接受實驗室生物安全課程至少八小時。實驗室工作人員每年應取得實驗室生物安全持續教育至少四小時。生物安全第三等級以上實驗室新進人員，應參加中央主管機關認可之生物安全訓練。Operators handling infectious biological materials shall complete the relevant biosafety training and pass the required tests before they are allowed to perform experiments. New hires in the laboratories shall receive at least 8 hours of laboratory biosafety training. Laboratory staff shall complete at least 4 hours of continuing biosafety education annually. New hires in Biosafety Level 3 (BSL-3) laboratories or above shall attend biosafety training recognized by the central competent authority. |
| 第九條Article 9 | 本校生物性實驗之各級操作人員應遵守本校「生物實驗安全作業手冊」之管理原則。Operators of biological experiments at all levels in KMU shall abide by the management principles specified in the KMU Biological Experiment Safety Operation Manual.BSL-2級以上實驗室負責人或管理人員得依前項作業手冊制訂該實驗室適用之管理守則及生物安全緊急應變計畫，生物安全緊急應變計畫需送交生安會審核。Directors or managers of BSL-2 laboratories or above may formulate an appropriate laboratory management guide and a biosafety emergency response plan in accordance with the aforementioned Operation Manual. The biosafety emergency response plan shall be forwarded to the IBC for review. |
| 第十條Article 10 | 實驗室持有、保存或處分第二級以上危險群微生物或生物毒素，應經生安會審核通過，始得為之。Laboratories shall be reviewed and approved by IBC before they may possess, store, or dispose of Risk Group 2 microorganisms or biological toxins or above.實驗室持有、保存或處分第三級以上危險群微生物或管制性生物毒素，除依前項規定辦理外，設置單位並應報中央主管機關核准，始得為之。For the possession, storage, or disposal of Risk Group 3 microorganisms or controlled biological toxins or above, the unit shall not only get approval as mentioned above, but also declare to and get approval from the central competent authority. |
| 第十一條Article 11 | 實驗室應定期盤點其持有、保存之第二級以上危險群微生物或生物毒素品項及數量。發現有不符或遺失等異常事件時，應立即通報生安組。Laboratories shall regularly inventory the items and quantities of Risk Group 2 microorganisms or biological toxins or above in their possession or storage. If discrepancies or losses are detected, the Biosafety Division shall be notified immediately. |
| 第十二條Article 12 | 操作感染性生物材料實驗所需BSL實驗室等級規範：Laboratory BSL specifications required for operating experiments that involve infectious biological materials:1. 操作及培養疾管署列出之Risk Group 2 (RG2)感染性生物材料，必須在BSL-2級實驗室操作。
2. Risk Group 2 (RG2) infectious biological materials, as listed by CDC, shall be handled and cultured in a BSL-2 laboratory.
3. 利用Adenovirus、Retrovirus或Lentivirus做為載體進行基因重組，及將此載體轉染至BSL-1或BSL-2細胞株之研究，必須在BSL-2級實驗室操作。
4. Research involving the use of Adenovirus, Retrovirus, or Lentivirus as vectors for genetic recombination, and transfecting these vectors into BSL-1 or BSL-2 cell lines shall be done in a BSL-2 laboratory.
5. 若利用Retrovirus、Lentivirus轉染之基因為已確知之致癌基因(oncogene)，需於具備Class II B2全外排BSC之BSL-2級實驗室操作，並遵守BSL-3級之操作規範，增加個人防護具之使用。
6. If the gene transfected using Retrovirus or Lentivirus is a known oncogene, the work must be done in a BSL-2 laboratory equipped with a Class II B2 biological safety cabinet (BSC) and must adhere to the BSL-3 operational protocols, including the use of additional personal protective equipment.
7. 以上項目每次操作最後總量不得超過200 ml，且總病毒數不得超過1×109。
8. The total volume of the above items shall not exceed 200 ml at the end of each operation, and the total viral count shall not exceed 1×109.
9. 以上(1)至(4)項實驗過程若需使用具揮發性之有毒化學物質，必需於具備Class II B2全外排BSC之BSL-2級實驗室操作。
10. If the experimental processes from (1) to (4) above require the use of volatile toxic chemicals, they must be performed in a BSL-2 laboratory equipped with a Class II B2 BSC.
11. 若不利用第(2)項所列之病毒載體做基因轉殖研究，只是進行培養，以及利用Liposome或電極轉染基因於被ATCC歸類為BSL-2級之人類細胞株做研究，若該細胞株無感染能力，可放寬於一般細胞培養室操作。
12. If the viral vectors mentioned in (2) are not used in the gene transformation research, while only culturing is performed and liposomes or electroporation transfected genes are used in BSL-2 human cell lines as classified by ATCC, and if these cell lines are non-infectious, the work may be done in a standard cell culture room.
 |
| 第十三條Article 13 | 若實驗操作者未於所申請之BSL-2級實驗室操作實驗，經查獲或舉報屬實，將禁止該員操作BSL-2級實驗一個月，並需至疾管署數位學習網上滿十小時生安組指定之訓練課程及通過考試後，始得再次操作。再犯者，禁止操作BSL-2級實驗三個月，並可連續處罰。該計畫主持人或指導教授需至疾管署數位學習網上滿十小時生安組指定之訓練課程及通過考試後，始得再次申請使用BSL-2級實驗室。累犯者，未來一年內本委員會將不審查及同意其二級以上基因重組或感染性生物材料異動之申請，亦不得申請使用BSL-2級實驗室。If an experiment operator fails to perform an experiment in the approved BSL-2 laboratory, and the situation is reported and verified, he/she will be prohibited from performing BSL-2 experiments for one month, and has to complete 10 hours of online training on the CDC digital learning website specified by the Biosafety Division and pass the exam before resuming operations. In case of a second violation, the operator will be prohibited from performing BSL-2 experiments for 3 months, with the possibility of repeated penalties. The project’s principal investigator or advisor shall also complete the 10-hour online training on the CDC digital learning website specified by the Biosafety Division and pass the exam before re-applying for the use of the BSL-2 laboratory. For repeated violations, the Committee will decline the operator’s requests for the review or consent of Level 2 gene recombination or changes involving infectious biological materials in the coming one year; the operator is also not allowed to apply for the use of the BSL-2 laboratory. |
| 第十四條Article 14 | 若計畫主持人或指導教授本人未確實於申請之BSL-2級實驗室操作實驗，經查獲或舉報，禁止該員操作BSL-2級實驗一個月，並需至疾管署數位學習網上滿二十小時生安組指定之訓練課程及通過考試後，始得再次操作。累犯者，未來一年內本委員會將不審查及同意其二級以上基因重組或感染性生物材料異動之申請，亦不得申請使用BSL-2級實驗室。If the principal investigator or advisor fails to perform an experiment in the approved BSL-2 laboratory, and the situation is reported and verified, he/she will be prohibited from performing BSL-2 experiments for one month, and has to complete 20 hours of online training on the CDC digital learning website specified by the Biosafety Division and pass the exam before resuming operations. In case of repeated violations, the Committee will decline his/her requests for the review or consent of Level 2 gene recombination or changes involving infectious biological materials in the coming one year; the investigator or advisor is also not allowed to apply for the use of the BSL-2 laboratory. |
| 第十五條Article 15 | 實驗單位應依本校實驗室生物性廢棄物處理清運流程處理廢棄物。The unit doing the experiments shall dispose of the waste according to the KMU Laboratory Biological Waste Disposal and Collection Procedures. |
| 第十六條Article 16 | 生安組於有重大安全疑慮時，得要求全部或部分停止相關感染性生物材料之使用或停止實驗室之運作，並經生安會確認安全無虞及同意後重新使用，必要時，得報中央主管機關核備。In case of significant safety concerns, the Biosafety Division may require partial or complete cessation of the use of infectious biological materials or suspension of laboratory operations. Resumption of use is only allowed after the IBC has confirmed the safety and given approval. The central competent authority may also be notified for future reference, if necessary. |
| 第十七條Article 17 | 運送感染性生物材料，應符合中央主管機關另定之三層包裝規定；以空運方式運送感染性生物材料，其包裝規定並應遵照目的事業主管機關規定辦理。感染性生物材料於運送途中發生洩漏情事時，運送人員應立即通知實驗室負責人及生安組為必要之處置。The transportation of infectious biological materials shall be in compliance with the triple-layer packaging regulations set down by the central competent authority. For air transportation of infectious biological materials, packaging shall also adhere to the regulations of the relevant authorities.In the event of a leakage during transportation of the infectious biological materials, the transport workers shall notify the laboratory director and the Biosafety Division for necessary actions. |
| 第十八條Article 18 | 各單位、學生及社團等舉辦各項活動或營隊時，內容若涉及操作感染性生物材料與使用微生物實驗室時，應向生安組提出申請，經生安會委員審核通過後始得進行。When organizing activities or camps that involve and handle infectious biological materials or use microbiology laboratories, the units, students, and clubs shall submit an application to the Biosafety Division. The activities should only be held after IBC has reviewed and approved the activities/camps. |
| 第十九條Article 19 | 違反本辦法者，應予以警告限期改善，並視情節輕重，提報生安會，如情節重大者提行政會議報告，違反規定之人員與單位主管應列席會議說明。A warning requiring improvement by a specific deadline shall be given to those who have violated these Regulations, and the IBC shall be informed depending on severity of the situation. In case of serious violations, the matter will be reported to the administrative meeting, and the violator and the head of unit involved shall attend the meeting to provide an explanation. |
| 第二十條Article 20 | 違反本辦法而導致環境損害或人員傷害，相關罰則分擔原則依本校「環安衛相關罰款分擔原則」及其他相關法令辦理。Penal provisions for violations of these Regulations causing environmental damage or personal injury shall be based on the KMU Principles of Environmental Protection, Safety and Health Fines Sharing and other relevant law and regulations. |
| 第二十一條Article 21 | 本辦法經生安會及行政會議通過，陳請校長核定後，自公布日起實施，修正時亦同。The Regulations shall be passed by IBC and the Administrative Meeting and submitted to the President for approval and then implemented on the date of promulgation and shall apply to subsequent amendments. |