**高雄醫學大學生物安全會設置要點**

**Kaohsiung Medical University**

**Directives for Establishment of Biosafety Committee**

| 95.01.18高醫校法字第0950100002號函公布  98.11.24九十八學年度第一次生物實驗安全委員會通過  99.01.14九十八學年度第六次行政會議通過  99.02.01高醫研發字第0991100425號函公布  101.02.14 一００學年度第3次生物實驗安全委員會議修訂通過  101.04.12 一００學年度第9次行政會議通過  101.05.21高醫環安字第1011101377號函公布  103.06.30 102學年度第4次生物實驗安全委員會議修訂通過  103.07.03 102學年度第10次行政會議通過  103.08.21 高醫環字第1031102679號函公布  105.04.14 104學年度第9次行政會議通過  108.01.11 107學年度第1次生物安全會通過  108.09.12 108學年度第2次行政會議通過  108.10.21 高醫環安字第1081103515號函公布 |
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January 18, 2006 Promulgated via the KMU official letter Hsiao Fa Tzu No. 0950100002

November 24, 2009 Passed by the 1st Biological Experiment Safety Committee meeting in Academic Year 2009-2010

January 14, 2010 Passed by the 6th Administrative Meeting in Academic Year 2009-2010

February 1, 2010 Promulgated via the KMU official letter Yan Fa Tzu No. 0991100425

February 14, 2012 Amended and passed by the 3rd Biological Experiment Safety Committee meeting in Academic

Year 2011-2012

April 12, 2012 Passed by the 9th Administrative Meeting in Academic Year 2011-2012

May 21, 2012 Promulgated via the KMU official letter Huan An Tzu No. 1011101377

June 30, 2014 Amended and passed by the 4th Biological Experiment Safety Committee meeting in Academic

Year 2013-2014

July 3, 2014 Passed by the 10th Administrative Meeting in Academic Year 2013-2014

August 21, 2014 Promulgated via the KMU official letter Huan Tzu No. 1031102679

April 14, 2016 Passed by the 9th Administrative Meeting in Academic Year 2015-2016

January 11, 2019 Passed by the 1st Biosafety Committee meeting in Academic Year 2018-2019

September 12, 2019 Passed by the 2nd Administrative Meeting in Academic Year 2019-2020

October 21, 2019 Promulgated via the KMU official letter Huan An Tzu No. 1081103515

| 一、  Article 1 | 高雄醫學大學(以下簡稱本校)為推動生物實驗安全有關工作，且依衛生福利部疾病管制署「感染性生物材料管理辦法」第九條之規定，設置生物安全會(以下簡稱生安會)，並訂定本要點。  Kaohsiung Medical University (KMU) formulates the KMU Directives for Establishment of Biosafety Committee to uphold biological experiment safety-related work and sets up the Biosafety Committee (BSC) in accordance with Article 9 of the Regulations Governing Management of Infectious Biological Materials by Taiwan Centers for Disease Control, Ministry of Health and Welfare. |
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| 二、  Article 2 | 本校生安會為生物安全政策及監督之權責單位，職責如下：  BSC is the competent authority in charge of the biosafety policies and the supervision thereof, and its duties include:   1. 訂定實驗室生物安全、生物保全管理政策及規定。   (1) Formulate the laboratory biosafety and biosecurity management policies and regulations.   1. 審核第二級以上危險群病原體或生物毒素之持有、保存、使用、處分或輸出入。   (2) Review the possession, storage, use, disposal, or import and export of pathogens or biotoxins in Risk Group 2 or above.   1. 審核使用第二級以上危險群病原體或生物毒素之實驗室生物安全等級。   (3) Review the biosafety level of laboratories that use pathogens or biotoxins in Risk Group 2 or above.   1. 審核實驗室、保存場所之生物安全、生物保全緊急應變計畫。   (4) Review the biosafety and biosecurity emergency response plans of laboratories and storage facilities.   1. 審核實驗室、保存場所之新建、改建、擴建、啟用或停止運作計畫。   (5) Review the construction, reconstruction, expansion, inception and termination of use of laboratories and storage facilities.   1. 審核實驗室、保存場所之生物安全、生物保全爭議事項。   (6) Review biosafety and biosecurity disputes of laboratories and storage facilities.   1. 辦理每年實驗室、保存場所之生物安全、生物保全內部稽核及缺失改善。   (7) Hold the annual biosafety and biosecurity internal audits and improvement of drawbacks of laboratories and storage facilities.   1. 辦理實驗室、保存場所人員之生物安全、生物保全訓練，及人員知能評核活動。   (8) Organize biosafety and biosecurity training, as well as staff evaluation programs for the personnel of laboratories and storage facilities.   1. 規劃或辦理實驗室、保存場所人員健康檢查及建立健康狀況異常監控機制。   (9) Plan and arrange health checkups for the personnel of laboratories and storage facilities, and develop a health anomaly monitoring mechanism.   1. 審核及督導其他有關感染性生物材料、實驗室、保存場所之生物安全、生物保全管理事項。   (10) Review and supervise other matters relating to biosafety and biosecurity management of infectious biological materials, laboratories, and storage facilities.   1. 處理、調查及報告實驗室、保存場所之生物安全、生物保全意外事件。   (11) Handle, investigate, and report biosafety and biosecurity accidents of laboratories and storage facilities. |
| 三、  Article 3 | 本校生安會以副校長為主任委員，並置委員九至十三名，總幹事一名。除環安室主任、營繕組組長、研發處研究資源組組長為當然委員外，其餘委員由校長遴聘本校具生物相關專長之教師擔任之。生安會委員為無給職，任期為一年，期滿得續聘。生安會因審查研究計畫案之需要，另置計畫審查委員若干名，由校長遴聘校內外相關領域教師或專家擔任之  BSC shall comprise 9 to 13 members, with one chief executive, and the Senior Vice President shall be the chairperson. Director of the Office of Environmental Protection, Occupational Safety and Health, Chief of the Division of Construction and Maintenance, and Director of the Center for Research Resources and Development are ex-officio members of SBC, and the other members shall be selected and appointed by the President from KMU’s faculty members specialized in biology-related areas. SBC members are non-paid and serve a term of one year, renewable upon expiration. For the need to review research projects, SBC shall also have a few project review committee members, to be selected and appointed by the President from teachers or experts in related disciplines inside or outside KMU. |
| 四、  Article 4 | 生安會每學期至少召開會議一次，由主任委員召集之，必要時得召開臨時會議。生安會開會時，得邀請校外相關專家學者出席。  BSC shall hold a meeting at least once in every semester, to be convened by the chairperson; interim meetings may be held when necessary. When a BSC meeting is in session, related experts and scholars outside KMU may be invited to attend the meeting. |
| 五、  Article 5 | 生安會會議應有全體委員二分之一以上出席始得開會，並經出席委員二分之一以上通過始得決議。  A BSC meeting shall be held with a quorum of more than half of all members, and resolutions shall be made with the consents of more than half of the attending members. |
| 六、  Article 6 | 本要點經行政會議審議通過後，自公布日起實施，修正時亦同。  These Directives shall be reviewed and passed by the Administrative Meeting and then implemented on the date of promulgation and shall apply to subsequent amendments. |