The minutes of the Academia Sinica (AS) Institutional Biosafety Committee (IBC) second meeting in 2024

Time/Date: 10 am, July 17, 2024 (Wednesday)

Location: 2F, Meeting Room, Yellow Tile Building

Chair: Director Tang K. Tang **Minute Taker**: Joanne Hu

Committee Members:

Wen-Chao Wu 吳文超, Sue Lin-Chao 林淑端, Ya-Jen Chang 張雅貞, Guang-Chao Chen 陳光超, Hsuanyu Chen 陳璿宇, Yung-Che Tseng 曾庸哲, Sen-Lin Tang 湯森林, Show-Yi Yang 楊秀宜, Hsin-Hung Yeh 葉信宏, Ting-Jen Cheng 鄭婷仁, Charles Lai 賴品光(Absent), Erh-Min Lai 賴爾珉(Absent) (Listed in order of Chinese surname strokes)

Other Attendees:

Biosafety Office: Grace Wu 吳秋錦, Jhih-Hong Liou 劉志鴻, Cheng-Nan Chen 陳政男, Ya-Chih Chang 張雅智

BioTReC: Wen-Chun Claire Liu 劉玟君, Yi-An Ko 柯怡安

A. Chair's Opening Remarks: Omitted

B. Confirmation of Previous Meeting Minutes and Report on Follow-Up Actions:

The minutes of the Academia Sinica (AS) Institutional Biosafety Committee (IBC) first meeting in 2024 were approved.

Follow-Up Action (FUA) Items from the Previous Meeting:

1. 110-1 FUA 7, 112-1 FUA 2 and 3, 113-1 FUA 1: Please continue to follow up on the amendment schedule of the Centers for Disease Control (Taiwan CDC) and coordinate to revise the “Guidelines for the Establishment and Biosafety Management of the Academia Sinica Institutional Biosafety Committee” and the “Academia Sinica Biosafety Office Implementation Guidelines.” This matter will remain under ongoing supervision.
2. 112-1 FUA 7, 112-3 Discussion 2, 113-1 FUA 2: Regarding the proposal to establish a backup location for the surveillance footage and access control records of the high-containment laboratories, it shall proceed as outlined in the following resolutions. This

matter will remain under ongoing supervision.

(1) According to the regulations of the Taiwan CDC, the backup retention period for surveillance footage and access control records of the high-containment laboratories at AS Institutes and Research Centers, are revised to three months. AS high-containment laboratories are requested to adjust and configure their hardware specifications in accordance with the newly revised backup retention period.

(2) Approval is granted to establish backup locations for the surveillance footage and access control records of the high-containment laboratories at the Biomedical Translation Research Center (BioTReC) in Room B553 (Fifth floor of Building B, National Biotechnology Research Park).

3. 112-2 FUA 4, 112-1 Discussion 5, 113-1 FUA 3: The members had no objections. This matter will no longer be under supervision.
4. 112-3 Discussion 1, 112-4 Discussion 3, 113-1 FUA 5: The members had no objections. This matter will no longer be under supervision.
5. 112-4 FUA 2, 113-1 FUA 7: With regard to the hierarchy and roles of the Institute and Research Center supervisors and the Biosafety Management Committee within the biosafety management organizational structure, these should be revised according to the committee members' recommendations. At the Institute and Research Center level, one biosafety supervisor should be appointed by the Institute or Research Center. The qualifications are not limited to the deputy director level of research personnel and the position may also be held concurrently by the chair of the Institute and Research Center's Biosafety Management Committee. The revised organizational structure chart should be discussed with each Institute or Research Center before submitting it to the supervisory meeting for discussion. This matter will no longer be under supervision.
6. 112-4 Discussion 2, 113-1 FUA 8: The Biosafety Office is currently drafting the "Academia Sinica Institutional Biosafety Committee Application Procedures for the Export/Import of Infectious Biological Materials" (draft). The draft will include a simplified process for the application and approval of RG1 pathogen exports/imports. Feedback will be solicited via email from committee members and all Institutes and Research Centers before final approval and implementation. This matter will remain under ongoing supervision.
7. 113-1 Report on Chair's Directive 2: The members had no objections. This matter will no longer be under supervision.
8. 113-1 Discussion 3 Resolutions: The members had no objections. This matter will no

longer be under supervision.

9. 113-1 Discussion 5 Resolutions: The members had no objections. This matter will no longer be under supervision.

C. Routine and Project Reports:

1. The Biosafety Affairs Report for the second quarter of this year (April to June) is detailed in the meeting presentation (omitted).
2. The name of the Biosafety Management Committee of the Research Center for Applied Sciences is the "Environmental Safety, Health, and Public Affairs Committee." This has been officially noted for record.
3. Project report for the second quarter of this year (April to June): The Biosafety Office commissioned two procurement projects this year:
   (1) Production of a digital course on laboratory biosafety and biosecurity (English version).
   (2) A consultancy project for the implementation of a risk assessment system for BSL-2 and higher laboratories.

D. Discussion

Discussion Item 1: A proposal to convene the "Academia Sinica Biosafety High-containment Laboratory Biosafety Expert Advisory Meeting," was discussed.

Resolution: The Biosafety Office is requested to proceed according to the planned schedule.

Discussion Item 2: A proposal to optimize the biological research project review process was discussed.

Resolution:

(1) The proportion of advisory committee members to assist with the review of research projects should be based on the number of project applications from each Institute and Research Center. At the end of the year, an official letter will be issued to all Institutes and Research Centers requesting that the performance of researchers who assist in reviewing AS biological research projects be included in their performance evaluations.

(2) External experts and scholars in the field of biology should be invited to serve as reviewers for the special or high-biosafety-risk research projects at AS.

(3) To effectively assist in ensuring the accuracy and completeness of research project application content, the Biosafety Office may request that the principal investigators

or designated personnel visit the office to discuss and confirm the biosafety details of the research project application.

(4) To rationalize and institutionalize the process for obtaining approval documents for biological research projects in AS, all Institutes and Research Centers should be informed that principal investigators needing to obtain the biosafety review consent must submit their applications as early as possible through the Academia Sinica Institutional Biosafety Committee System. Biosafety managers in each Institute and Research Center should assist in reminding their respective Institute and Research Center about the timeliness of each stage of preliminary review.

Applications for project reviews submitted to the Biosafety Office will require approximately three weeks for processing, including administrative checks by the Biosafety Office (seven days), and review by committee members (14 days). This three-week processing time does not include any additional time required for returning and resubmitting applications due to incomplete or incorrect information. Relevant regulations will also be published on AS website.

Discussion Item 3: Discrepancies between the personnel information in the Academia Sinica personnel system and the "Academia Sinica Staff Learning Hours Query and Management System." were discussed.

Resolutions: Please inform all Institutes, Research Centers and relevant departments of the following matters.

(1) Institutes and Research Centers are requested to remind personnel in their respective biological laboratories (the Laboratories) or biological material banks (BMBs) to promptly update their information in the Academia Sinica personnel system when there are personnel changes.

(2) The Personnel Office and the Department of Information Technology Services are requested to assist in reviewing and ensuring the consistency of personnel information between the Academia Sinica personnel system and the Academia Sinica Staff Learning Hours Query and Management System.

Discussion Item 4: The biosafety training requirements for personnel involved in biological experiments at AS, as well as the revision of biosafety training hours for staff in various laboratories/BMBs were discussed.

Resolutions:

(1) The "Regulations for Biosafety Training and Assessment of Personnel in the Biological Laboratories and Biological Material Banks of Academia Sinica" should be revised to incorporate the following requirements (to be promoted in 2024 and implemented in 2025).

i. All laboratory/BMB personnel (including supervisors, managers, researchers, and research technicians) and support staff (including transportation and cleaning personnel) must complete the required biosafety training hours as specified in the attached document, according to the type of laboratory/BMB.

ii. Principal investigators must complete the required biosafety training hours corresponding to the risk group (RG) level of the pathogens involved in their research projects. For example, a principal investigator working with RG2 pathogens must complete eight hours of courses or nine hours of courses if conducting animal experiments.

iii. Visitors, personnel not affiliated with the aforementioned Institutes and Research Centers, and internal/external auditors are exempt from the relevant biosafety training courses if accompanied by a designated laboratory/BMB staff member.

iv. New personnel (excluding cleaning staff) must undergo an assessment after completing their training. Only those who pass the assessment are permitted to work in the laboratory/BMB.

v. New personnel in BSL-2, BSL-2+, ABSL-2 laboratories, and regulated BMBs (i.e., those storing RG2 pathogens and biological toxins) must complete eight hours of courses (BSL-2/BSL-2+) or nine hours of courses (ABSL-2) within seven working days of joining the institution.

vi. New cleaning staff are required to complete two hours of biosafety training course, while current staff must complete one hour of biosafety training course.

(2) The course topics and hours for various staff members that are planned for implementation in 2025 should be published on the AS Institutional Biosafety Committee website and promoted at the next meeting of Institute and Research Center Biosafety Managers (Biosafety Managers).

Discussion Item 5: A draft proposal for assigning administrators for the "Academia Sinica Biosafety High-containment Laboratory Surveillance and Access Control Backup

Recording Storage Management Regulations" was discussed.

Resolution: Regarding the assignment of managers for the high-containment laboratory surveillance and access control record storage rooms at each Institute or Research Center, both the high-containment laboratory manager and the biosafety manager of the respective Institute or Research Center should jointly serve as the storage room managers. The division of responsibilities for the storage room managers should be determined by the respective Institute or Research Center.

Discussion Item 6: The handling of infectious biological materials and the management of laboratory (BMB) disposal processes prior to the retirement or departure of laboratory (BMB) supervisors and staff at each Institute and Research Center, was discussed.

Resolutions:

(1) Feedback should be solicited on the draft of the "Academia Sinica Institutional Biosafety Committee Regulations for the Disposal and Acknowledgment of Personnel Retiring or Departing from Institutes and Research Centers Holding Infectious Biological Materials and Managing Laboratories (BMB)," from each Institute and Research Center. This topic will be discussed at the next meeting.

(2) Until the new revised regulations are issued, please proceed with expanding the current "Academia Sinica Infectious Biological Materials List" form to maintain the proper handling procedures for retiring or departing personnel.

Discussion Item 7: The provision of equipment, blood collection tubes, and consumables required to implement the policy for baseline serum blood sample preservation in laboratories of the Institutes and Research Centers, coordinated with the Infirmary and Institutional Biosafety Committee, was discussed.

Resolution: Due to time constraints, this matter will be discussed at the next meeting.

E. Temporary Motions: None

F. Adjournment: 12:20 pm

Attachment: Overview of Biological Safety Training Course Topics and Hours for Various Types of Laboratory/BMB Staff of Academia Sinica (to be implemented in 2025)

The attachment is only available in Chinese. For those who need to take the English version of the course, please go to https://biosafety.sinica.edu.tw/archives/a065e00db51ac398 for more information.

Category	Topic	Sub-topic	ABSL-3 Lab	BSL-3 Lab	ABSL-2 Lab	BSL-2+/ BSL-2 Lab	ABSL-1 Lab	BSL-1 Lab	RG2 BMB	General BMB	Transportation staff	cleaning staff
新進人員	生物風險評鑑		1	1	1	1			1			
	法規、組織運作及管理審查	法規規範	1	1	1	1			1			
		組織運作	1	1								
	生物安全及生物保全概論						1	1		1	1	0
	優良微生物操作技術及內部稽核		1	1								
	實驗動物安全		1		1							
	生物保全		1	1	1	1			1			
	健康監測及人員訓練		1	1	1	1			1			
	個人防護裝備及安全設備		2	2	1	1			1			
	負壓設施及通風空調系統	負壓設計	2	2								
		空調系統	1	1								
	消毒及滅菌	滅菌設備	1	1	1	1			1			
		消毒除汙	1	1								
	應變計畫及生安事故通報與演習	應變計畫	1	1	1	1			1		1	1
		應變演練	1	1								

Category	Topic	Sub-topic	ABSL-3 Lab	BSL-3 Lab	ABSL-2 Lab	BSL-2+/ BSL-2 Lab	ABSL-1 Lab	BSL-1 Lab	RG2 BMB	General BMB	Transportation staff	cleaning staff
	感染性物質運送及廢棄物處理		1	1	1	1	1	1	1	1	1	1
	Hours		17	16	9	8	2	2	8	2	3	2
在職人員	Unrestricted topic/sub-topic											
	Hour(s)		4	4	4	4	1	1	4	1	1	1