STANDARD OPERATING PROCEDURES (SOPs)

prepare by

Institutional Biosafety Committee of Chulabhorn International College of Medicine, Thammasat University

Contents

Institutional Biosafety Committee of Chulabhorn International College of Medicine, Thammasat University

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Prepared by	Dr. Teva Phanaksri	**Reviewered by**	Prof. Dr. Ratha-korn Vilaichone	**Approval by**	Prof. Dr. Adis Tasanarong	9 April 2021	

1. Objective

To serve as a guideline for CICM-BCC, to operate according to the consideration of biosafety level and for selection of the appropriate laboratory for research projects.

2. Scope

For CICM-BCC and the operators to educate to the standards of biosafety level and appropriate laboratory selection for research projects following the law of Pathogens and Animal Toxins Act, B.E. 2558 (2015).

3. Principle

To serve the safety of researchers, co-researchers, and the public. This guideline aims to operate the research projects that study microorganisms, biological substances, and microbial samples which are pathogens listed under the law of Pathogens and Animal Toxins Act, B.E. 2558 (2015) and Ministry of Public Health announcement approximately characteristic of a place of production or the possession of pathogens and animal toxins B.E. 2561.

4. Terminology and abbreviation

4.1 BSL1 represents a biosafety laboratory level 1

4.2 BSL2 represents a biosafety laboratory level 2

4.3 CICM-BCC refers to Institutional Biosafety Committee of Chulabhorn International College of Medicine, Thammasat University.

4.4 TU-IBC refers to Institutional Biosafety Committee, Thammasat University.

5. Responsibilities

5.1 Institutional Biosafety Committee of Chulabhorn International College of Medicine, Thammasat University

5.2 Laboratory committee of Chulabhorn International College of Medicine, Thammasat University

5.3 Research Supporting Office

5.4 Operator of Chulabhorn International College of Medicine, Thammasat University

5.5 Operation personnel of Chulabhorn International College of Medicine, Thammasat University

5.6 Researchers

6. Related documents

6.1 Application of biosafety laboratory level consideration form (CICM-BCC-FA-001)

6.2 Application of biosafety laboratory level 2 form (CICM-BCC-FA-002)

6.3 Biosafety laboratory level 2 report form (CICM-BCC-FA-003)

7. References

7.1 The law of Pathogens and Animal Toxins Act, B.E. 2558 (2015)

7.2 Ministry of Public Health announcement approximately characteristic of a place of production or the possession of pathogens and animal toxins B.E. 2561.

7.3 Ministry of Public Health announcement on the study of disease control, protection, and treatment B.E. 2561.

8. Procedures

8.1 Principal investigator who belong to Chulabhorn International College of Medicine

8.1.1 Principal investigator will be the person who considers and selects the appropriate biosafety laboratory level for a research project.

8.1.2 In the case of BSL1, the researcher can do the research without any requirement.

8. 1. 3 In the case of BSL2, the principal investigator sends the research project name, accompanied by a TU‑IBC approval document, to the Operation personnel of Chulabhorn International College of Medicine, Thammasat University.

8.2 Principal investigators who are persons from other divisions, but with a co-investigator belonging to the Chulabhorn International College of Medicine.

8.2.1 The principal investigator sends the request document from their division to the dean of Chulabhorn International College of Medicine combine with a proposal and related documents.

8.2.2 In case the research is not associated with biosafety, the vice dean of research and innovation affairs is the person who makes the decision. On the other hand, if research projects are associated with biosafety, the document will be subject to decision by the CICM-BCC.

8.2.3 CICM-BCC will consider the permission of the research project. In case of approval, the research project will receive a permission document for biosafety laboratory level 2 (BSL2).

8.3 Principal investigators who are persons from other divisions and do not have a co‑investigator belonging to the Chulabhorn International College of Medicine

8.3.1 The principal investigator sends a request document from their division to the dean of Chulabhorn International College of Medicine, combined with a proposal and related documents.

8.3.2 If the research is not associated with biosafety, the vice dean of research and innovation affairs is the person who makes the decision. On the other hand, for research projects associated with biosafety, the document will be subject to a decision by the CICM-BCC.

8.3.3 CICM‑BCC will consider permission of the research project. In case of approval, the research project will receive a permission document for biosafety laboratory.

8.3.4 The office of research, services, and administrative support will provide a quotation of laboratory fees for that research project.

8.4 The office of research, services, and administrative support informs the operators, operation personnel, and the secretary of the CICM-BCC of operation of the research following the law of Pathogens and Animal Toxins Act, B.E. 2558 (2015).

8.5 After the laboratory is finished, the operation personnel (researchers) send the application of biosafety laboratory level 2 report form specifying the microorganism name, microorganism volume, number of products, and collection site.

8.6 All equipment and BSL-rooms will be reserved by using the research laboratory and lab equipment reservation system (online system) before doing any laboratory work.

Institutional Biosafety Committee of Chulabhorn International College of Medicine, Thammasat University

Title:	**Research operations in the BSL1 Research Laboratory of the CICM**				**Document control**	**Page : 1 / 3**	
					CICM-BCC-SA	**002**	**REV.01**
Prepared by	**Dr. Teva Phanaksri**	**Reviewed by**	**Prof. Dr. Ratha-korn Vilaichone**	**Approved by**	**Prof. Dr. Adis Tasanarong**	**Approved date**	**9 April 2021**

1. Objective

To be a guideline for research operations in the BSL1 Research Laboratory of the CICM

2. Scope

Guideline for eligible persons to study and understand research operations in the BSL1 Research Laboratory of the CICM according to the Pathogens and Animal Toxins Act, B.E. 2558 (2015)

3. Principle

Use of Group 1 Pathogens and Biosafety Level 1 in research of CICM according to the Pathogens and Animal Toxins Act, B.E. 2558 (2015) and the Notification of the Ministry of Public Health B.E. 2561 (2018), prescribing the characteristics of the Place of Production or Possession and Operation of Pathogens and Animal Toxins for the safety of operators, co-workers and community.

4. Definitions and abbreviations

4.1 CICM-BCC refers to the Institutional Biosafety Committee of Chulabhorn International College of Medicine, Thammasat University.

4.2 BSL1 refers to a biosafety level 1 laboratory.

5 Responsible personnel

5.1 Institutional Biosafety Committee of Chulabhorn International College of Medicine, Thammasat University.

5.2 Laboratory committee of Chulabhorn International College of Medicine, Thammasat University.

5.3 Research Supporting Office.

5.4 Operators of Chulabhorn International College of Medicine, Thammasat University.

5.5 Operation personnel of Chulabhorn International College of Medicine, Thammasat University.

5.6 Researchers.

6. Related Document

6.1 Form to request approval for access to BSL2 laboratories (CICM-BCC-FA-002)

7. References

7.1 Pathogens and Animal Toxins Act, B.E. 2558 (2015)

7.2 Notification of the Ministry of Public Health B.E. 2561 (2018), prescribing the Characteristics of the Place of Production or Possession and Operation of Pathogens and Animal Toxins

8. Operational processes

8.1 Eligible work in a BSL1 Laboratory.

8.1.1 Research without pathogens.

8.1.2 Use of Group 1 Pathogens in research without genetic engineering.

8.1.3 Use of Group 1 Pathogens in research with genetic engineering, which combines at least two different types of DNAs that pose a low risk.

8.1.4 Specimens derived from healthy humans and animals, such as blood, serum, plasma, body parts, organs, tissue, etc., are required for consideration and evaluation by the CICM-BCC.

8.1.5 Group 2 Pathogen-infected specimens derived from humans and animals such as blood, serum, plasma, body parts, organs, tissues, etc, which are clearly scientifically proven to be without contamination of pathogens, are required for consideration and evaluation by the CICM-BCC.

8.1.6 Group 2 Pathogen-infected specimens derived from humans and animals, such as blood, serum, plasma, body parts, organs, tissues, etc., which are disinfected by chemical and physical methods or others with ensured inactivation of pathogens, are required for consideration and evaluation by the CICM-BCC.

8.2 Operator and operation personnel should be informed before research is conducted in a BSL1 Research Laboratory.

8. 3 Researchers must conduct the research under the control of the operator and authorized operation personnel.

8.4 Researchers must conduct the research according to the Pathogens and Animal Toxins Act, B.E. 2558 (2015) and related Notification of the Ministry of Public Health.

8.5 Use of human and animal specimens in research, such as blood, serum, plasma, body parts, organs, tissues, etc. should be within the biosafety cabinet (BSC).

8.6 Close-toed shoes are mandatory.

8.7 During research operations, researchers must wear personal protective equipment including a lab coat, gloves, mask and/or eye protection that are suitable for each task.

8.8 After research operations, biological samples must be inactivated before putting in a biohazard waste container.

8.9 After research operations, researchers must use a suitable technique to reduce contamination before leaving the laboratory.

8.10 In case of an accident that leads to biological spill, manage following the instructions for biological spill response procedure as described in CICM-BCC-SA-008

8.11 Do not operate acidic, basic or flammable substances within biosafety cabinet (BSC)

8.12 Do not allow persons who do not conduct research to enter the laboratory

8.13 Do not directly use mouth suction to transfer substances with a pipette

8.14 Items unrelated to research are not allowed

8.15 Food and drink are prohibited

8.16 Do not insert or remove contact lenses while working in the laboratory

8.17 Do not use cosmetics while working in the laboratory

8.18 Do not use a mobile phone and touch a clean area such as a doorknob while wearing gloves

8.19 Use an elbow to push door holders or a foot to push a door carriage for sliding the door

8.20 Wash hands before leaving the laboratory

8.21 Unauthorized persons are strictly forbidden

Institutional Biosafety Committee of Chulabhorn International College of Medicine, Thammasat University

Title:	Research operations in the BSL2 Research Laboratory of the CICM	**Document control**	**Page: 1 / 6**
		CICM-BCC-SA 003	**REV.01**

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1. Objective

To be a guideline for research operations in the BSL2 Research Laboratory of the CICM

2. Scope

This procedure applied to all users who intend to work in BSL2 laboratories of the Chulabhorn International College of Medicine, to review the guideline prior to conducting research. This procedure has been developed with regard to the Pathogens and Animal Toxins Act, B.E. 2558 (2015).

3. Principle

This SOP is a guideline for conducting research in BSL2 laboratories involving pathogenic activity, including bacteria, fungi, viruses, parasites and non-pathogenic protein particles. Any research on prions, including any sample that has been contaminated with pathogenic protein particles, is not permitted. Moreover, this SOP is also for conducting research in BSL2 laboratories with activities related to any modern biotechnology that uses genetically modified organisms including pathogens, plants, humans and animals, specimens from both humans and animals, and/or hazardous biological substances. Bacterial and mold toxins are not permitted to carry out research on, to ensure the safety of researchers, co-workers and communities.

4. Definitions and abbreviations

4.1 CICM-BCC refers to the Institute Biosafety Committee of the Chulabhorn International College of Medicine, Thammasat University

4.2 TU-IBC refers to the Institutional Biosafety Committee, Thammasat University

4.3 BSL1 refers to a biosafety level 1 laboratory

4.4 BSL2 refers to a biosafety level 2 laboratory

5. Responsible personnel

5.1 Institute Biosafety Committee of the Chulabhorn International College of Medicine, Thammasat University

5.2 Laboratory committee of the Chulabhorn International College of Medicine, Thammasat University

5.3 Research supporting Office

5.4 Operator of the Chulabhorn International College of Medicine, Thammasat University

5.5 Operation personnel of Chulabhorn International College of Medicine, Thammasat University

5.6 Researchers

6. Related documents

6.1 Form to request consideration for biosafety level and laboratory (CICM-BCC-FA-001)

6.2 Form to request approval for access to BSL2 laboratories (CICM-BCC-FA-002)

6.3 Form to report access to BSL2 laboratories (CICM-BCC-FA-003)

6.4 SOP for handling and manipulation of human and animal samples that could be contaminated with Group 2 or 3 Pathogens* (CICM-BCC-SA-004)

6.5 SOP for production, import, export, transit, sale or possession of the pathogens and animal toxins (CICM-BCC-SA-005)

6.6 SOP for pathogen destruction (CICM-BCC-SA-006)

6.7 SOP for waste management (CICM-BCC-SA-007)

6.8 SOP for biological spill response (CICM-BCC-SA-008)

6.9 SOP for accident emergency response (CICM-BCC-SA-009)

7. References

Biosafety guidelines for modern biotechnology B.E. 2559 (2016), Technical Biosafety Committee (TBC), National Center for Genetic Engineering and Biotechnology. ISBN: 978-616-12-0476-1. http://www.biotec.or.th/biosafety/images/document/G01-Biosafety%20Guideline.pdf

8. Operational processes

Guideline for conducting research in a BSL2 laboratory

8.1 Scope of research

8.1.1 Research on Group 1, 2, or 3* pathogens where these pathogens must be listed or approved by the Chulabhorn International College of Medicine according to the Pathogens and Animal Toxins Act, B.E. 2558 (2015), and which require level consideration and risk assessment by the CICM-IBC.

8.1.2 Research on Type 1, 2 and 3* genetically modified organisms requires risk assessment by the CICM-BCC.

BSL2 Room A

Scope of research

1. Research on human and animal specimens which may be infected with bacteria, fungi, viruses, and parasites classified as Group 1, 2 and 3* pathogens.

2. Research on human and animal specimens which may be infected with genetically engineered bacteria, fungi, viruses and parasites.

3. Research on Group 1 Animal Toxins

BSL2 Room B

Scope of research

1. Research on cell cultures that are not contaminated with pathogens.

2. Research on cell culture hosts for viruses, parasites and other infectious agents classified as Group 1, 2 and 3* pathogens, which requires consideration and risk assessment by the CICM-BCC.

BSL2 Room C

Scope of research

1. Research on microorganisms that do not require host cells to multiply.

2. Research on bacteria, yeasts, and fungi classified as Group 1, 2, and 3* pathogens which requires consideration and risk assessment by CICM-BCC.

8.2 (Personal protective equipment: PPE)

8.2.1 Lab coat

8.2.2 Shoe cover for BSL2 laboratories

8.2.3 Gloves

8.2.4 Surgical mask or respirator

8.2.5 Goggles

8.2.6 Bouffant cap

8.2.7 Etc., other items that are proper to your work.

8.3 General guidelines for working in BSL2 Laboratory Rooms A, B, and C

Follow the SOP of BSL 1 laboratory, and

8.3.1 Researchers apply for a biosafety level and laboratory consideration from TU-IBC and must be approved completely prior to processing in BSL2 laboratories.

8.3.2 Reserve the rooms and instruments via online booking before accessing**.**

8.3.3 Researchers who access BSL2 laboratories are required to pass the training of SOP for biosafety of the Chulabhorn International College of Medicine, Thammasat University or the biosafety and biosecurity courses according to the Pathogens and Animal Toxins Act, B.E. 2558 (2015).

8.3.4 Researchers wear closed shoes before entering the anteroom.

8.3.5 All equipment is prepared and cleaned up before entering BSL2 laboratories. Pathogens and biological substances must be transferred through the double-wall container and put on the cart.

8.3.6 Research investigators must wear personal protective equipment (PPE) in the following order: shoe cover, hand washing, surgical mask, goggles, bouffant cap, lab coat and 2 pairs of gloves, respectively.

8.3.7 All work is ONLY done inside a biological safety cabinet.

8.3.8 Working area must be cleaned before and after every use by spraying disinfectant to tissue papers and wiping (do not spray disinfectant on the area directly).

8.3.9 After work, laboratory equipment and materials that have been in contact with pathogen-contaminated matter must be appropriately cleaned and immediately removed from laboratories according to

the SOP for pathogens destruction (CICM-BCC-SA-006) and the SOP for waste management (CICM-BCC-SA-007).

8.3.10 Personal protective equipment must be taken off in the following order: the first pair of gloves, bouffant cap, goggle, lab coat, shoe cover, the second pair of gloves, hand washing, surgical mask, and hand washing, and disposal into the prepared infectious waste container.

8.3.11 Hands must be washed before leaving the laboratories.

8.3.12 Mouth pipetting is prohibited; mechanical pipetting devices are to be used at all times.

8.3.13 Eating, drinking, smoking, and applying cosmetics are not allowed in the laboratories.

8.3.14 Substances used in all operations or research procedures are not allowed to be spread to other areas, or the spreading must be limited to the extent possible by conducting operations/procedures using biological safety cabinets.

8.3.15 Do not use concentrated acid and alkali, and equipment that will cause a flame in the biosafety cabinet (BSC).

8.3.16 If the production of Group 2 or 3* Pathogens is intended, production protocols must follow the standard procedures for production, import, export, sale, or possession of the pathogens and animal toxins (see document CICM-BCC-SA-005).

8.3.17 All sample tubes must be labelled, including species of pathogens, volume or number of pathogens, responsible person(s) and the date of production.

8.3.18 The pathogens and animal toxins must be stored only in the assigned area(s). Transportation of the pathogens must follow the standard procedures for production, import, export, sale, or possession of the pathogens and animal toxins (see document CICM-BCC-SA-005).

8.3.19 As soon as the research project is completed, the involved pathogens must be completely inactivated.

8.3.20 Researchers fill the form for the handover, destruction, and inactivation of pathogens and animal toxins according to the Notification of Minister of Public Health for the termination of production, import, export, sale, transit or possession of pathogens and animal toxins B.E. 2560 to report to CICM-IBC and TU-IBC.

8.4 Special (additional) guidelines for working in BSL2 Laboratory Rooms A, B, and C

8.4.1 The research principal and researchers must be responsible for the conduct and the incurred damage in case of non- compliance with the standard operating procedures (SOP) of the Chulabhorn International College of Medicine, Thammasat University and/or the Pathogens and Animal Toxins Act, B.E. 2558 (2015).

8.4.2 The research principal and researchers must only perform the research specified in the approved proposal.

8.4.3 The research principal and researchers must establish policies on how to proceed with the project. The researchers must be given instructions on the hazards and things that must be done before entering the laboratory, such as vaccination, practice, etc.

8.4.4 If there is any biological spill or accident, please follow the SOP on biological spill response (CICM-BCC-SA-008).

8.4.5 Samples used in the laboratories, such as serum or anything that may pose a risk to a person in the laboratory, should be kept in a suitable and limited access area.

8.4.6 Research on cell cultures without Group 1, 2 and 3* pathogens can be conducted in the BSL2 Laboratory Room B following the SOP for BSL2 Laboratory Room B.

1. Objective

To be the standard operating procedure (SOP) for handling and manipulation of human and/or animal samples that could be contaminated with Group 2 or 3 Pathogens* in a research laboratory setting.

2. Scope

For all individuals who intend to handle and manipulate human and/or animal samples that could be contaminated with Group 2 or 3 Pathogens* at the research laboratory of Chulabhorn International College of Medicine (CICM), to review the guidelines prior to executing the experiments.

3. Principle

This SOP is created corresponding to the PATHOGENS AND ANIMAL TOXINS ACT, B.E. 2558 (2015) and Notification of the Ministry of Public Health on Characteristics of the place for production or possession of and operations on pathogens and animal toxins, B.E. 2561 (2018), in relation to laboratory characteristics, instruments and equipment as well as security systems and quality systems in order to provide and ensure safety and prevention of harm to persons, the environments and the public. Handling and manipulation of human and/or animal samples that could be contaminated with Group 2 or 3 Pathogens* must be operated in a biosafety level 2 (BSL2) laboratory that allows unidirectional airflow and has an exhaust air duct. There also must be protocols or procedures in preventing the dissemination of pathogens and animal toxins.

4. Definitions and abbreviations

4.1 CICM-BCC refers to the Biosafety Control Committee of the Chulabhorn International College of Medicine, Thammasat University

4.2 BSL2 refers to a biosafety level 2 laboratory

5. Responsible personnel

5.1 Biosafety Control Committee of the Chulabhorn International College of Medicine, Thammasat University

5.2 Laboratory committee of the Chulabhorn International College of Medicine, Thammasat University

5.3 Research supporting Office

5.4 Operator of the Chulabhorn International College of Medicine, Thammasat University

5.5 Operation personnel of the Chulabhorn International College of Medicine, Thammasat University

5.6 Researchers

6. Related document

6.1 Not available

7. References

7.1 PATHOGENS AND ANIMAL TOXINS ACT, B.E. 2558 (2015)

7.2 Notification of the Ministry of Public Health on characteristics of the place for production or possession of and operations on pathogens and animal toxins, B.E. 2561 (2018)

7.3 Notification of the Ministry of Public Health on termination of production, import, export, sale, transit or possession of pathogens and animal toxins, B.E. 2560 (2017)

8. Operational processes

8.1Operation date/time for each laboratory room, instrument and equipment must be booked via the online booking system before use.

8.2 Samples, including but not limited to blood, serum, plasma, tissues, organs, remains, etc., retrieved from healthy humans and/or animals, must be handled and manipulated in a class II biological safety cabinet (BSC) in the BSL1 or BSL2-Room A laboratory following the biological risk/safety assessment by the CICM-BCC.

8.3 Samples, including but not limited to blood, serum, plasma, tissues, organs, remains, etc., retrieved from humans and/or animals infected by Group 2 Pathogens* can be handled and manipulated in a class II BSC in the BSL1 laboratory following the biological risk/safety assessment by the CICM-BCC in

case that NO contamination of the samples by pathogens is detected at the time the samples arrive at the research facility.

8.4 Samples, including but not limited to blood, serum, plasma, tissues, organs, remains, etc., retrieved from humans and/or animals infected by Group 2 Pathogens* can be handled and manipulated in a class II BSC in the BSL1 laboratory following the biological risk/safety assessment by the CICM-BCC in case that the pathogens potentially contaminating the samples have been completely inactivated either by physical or chemical methods.

8.5 Samples, including but not limited to blood, serum, plasma, tissues, organs, remains, etc., retrieved from humans and/or animals infected by Group 2 Pathogens* that possess zoonotic potential must be handled and manipulated in a class II BSC in the BSL2-Room A laboratory following the biological risk/safety assessment by the CICM-BCC.

8.6 Multiplication of pathogens from samples, including but not limited to blood, serum, plasma, tissues, organs, remains, etc., retrieved from humans and/or animals infected by Group 3 Pathogens* is NOT permitted.

8.7 Handling and manipulation of samples, including but not limited to blood, serum, plasma, tissues, organs, remains, etc., retrieved from humans and/or animals infected by Group 3 Pathogens* are allowed only in case that multiplication of the pathogens from the samples does not exceed **30 milliliters** following the biological risk/safety assessment by the CICM-BCC. Possession of the pathogens must also be recorded following the standard procedures for production, import, export, sale, transit or possession of the pathogens and animal toxins (see document CICM-BCC-SOP-005).

8.8 Samples, including but not limited to blood, serum, plasma, tissues, organs, remains, etc., retrieved from humans and/or animals infected by Group 3 Pathogens* can be handled and manipulated in a class II BSC in the BSL2 laboratory following the biological risk/safety assessment by CICM-BCC in case that the pathogens potentially contaminating the samples have been completely inactivated either by physical or chemical methods.

8.9 If the production of Group 2 or 3 Pathogens* is intended, production protocols must follow the standard procedures for production, import, export, sale, transit or possession of the pathogens and animal toxins (see document CICM-BCC-SA-005).

8.10 Pathogen identification and volume or number of the pathogens as well as responsible person(s) and date of production must be labelled on the container or packages.

8.11 The pathogens and animal toxins must be stored only in the assigned area(s). Transportation of the pathogens must follow the standard procedures for production, import, export, sale, transit or possession of the pathogens and animal toxins (see document CICM-BCC-SA-005).

8.12 As soon as the research project is completed, the involved pathogens must be completely inactivated and the transfer, inactivation and verification of pathogens and animal toxins inactivation notification form on must be filled out and submitted to the CICM-BCC and the TU-IBC by the principle investigator according to Notification of the Ministry of Public Health on Termination of production, import, export, sale, transit or possession of the pathogens and animal toxins, B.E. 2560 (2017)

8.13 The pathogens intended to be used in any other projects must be registered in the CICM's licensed list of pathogen possession.

8.14 In case that the pathogens, resulting from or being an output of the research project, are NOT included in the aforementioned list,

8.14.1 If the investigators wish to inactivate the referred pathogens, they must follow the standard procedures for pathogen inactivation (see document CICM-BCC-SA-006) and solid waste management (see document CICM-BCC-SA-007) and submit a report indicating results of the pathogen inactivation to the CICM's operator or operation personnel within 24 hours according to Notification of the Ministry of Public Health on Termination of production, import, export, sale, transit or possession of pathogens and animal toxins, B.E. 2560 (2017)

8.14.2 If the investigators wish to retain the referred pathogens, they are obliged to notify the CICM's operator or operation personnel within 24 hours, so that the CICM-BCC can determine and provide the guideline for requesting an approval of pathogen registration, possession or inactivation.

*According to the PATHOGENS AND ANIMAL TOXINS ACT, B.E. 2558 (2015)

1. Objectives

To serve as a guide on how to produce, import, export, sell and possess pathogens and animal toxins for research projects aimed to be conducted at the 8th floor research laboratory, Co-operative Learning Center, Chulabhorn International College of Medicine, Thammasat University, Rangsit campus, by the CICM-BCC.

2. Scope

This is for studying and understanding how to produce, import, export, sell and possess pathogens and animal toxins for research projects aimed to be conducted at the 8th floor research laboratory, Co-operative Learning Center, Chulabhorn International College of Medicine, Thammasat University, Rangsit campus, provided by the CICM-BCC in accordance with the Pathogens and Animal toxins Act, B.E. 2558.

3. Principle

As the activities related with the production, import, export, transit, sale and possession of pathogens and animal toxins are regulated by the Pathogens and Animal toxins Act, B.E. 2558, any research project aimed to be conducted at the 8th floor research laboratory, Co-operative Learning Center, Chulabhorn International College of Medicine, Thammasat University, Rangsit campus, must abide by the Act. Therefore, those activities shall follow the act and the guidelines of conduct created by the CICM-BCC and TU-IBC, by using the principle of advance notification of both donor and recipient. The transportation of pathogens and animal toxins shall comply with the Pathogens and Animal toxins Act, B.E. 2558, the Hazardous substance Act, B.E. 2558 and other related legislations including land transportation, water transportation and air transportation, both domestic and international. In addition, packaging shall be up to standard criteria prescribed by the Pathogens and Animal toxins Act, B.E. 2558.

4. Definitions and abbreviations

4.1 CICM-BCC refers to the Institutional Biosafety Committee of the Chulabhorn International College of Medicine, Thammasat University

4.2 TU-IBC refers to the Institutional Biosafety Committee, Thammasat University

5. Responsible personnel

5.1 Institutional Biosafety Committee of the Chulabhorn International College of Medicine, Thammasat University

5.2 Laboratory committee of the Chulabhorn International College of Medicine, Thammasat University

5.3 Research supporting Office

5.4 Operator of the Chulabhorn International College of Medicine, Thammasat University

5.5 Operation personnel of the Chulabhorn International College of Medicine, Thammasat University

5.6 Researchers

6. Related documents

6.1 The notification of the ministry of health on transportation, transfer, destruction and inactivation of pathogens and animal toxins, B.E. 2561.

6.2 The notification of the department of medical sciences on the notice of transfer, destruction and examination after destruction of pathogens and animal toxins.

6.3 The notice of transfer, destruction and examination after destruction of pathogens and animal toxins in accordance with the notification of the ministry of health on the finishing of production, import, export, sale, transit and possession of pathogens and animal toxins B.E. 2561.

7. References

7.1 The Pathogens and Animal toxins Act, B.E. 2558. (2015)

7.2 The notification of the ministry of health on characteristics of the place of production or possession, and conduct of pathogens and animal toxins, B.E. 2561. (2018)

7.3 The Hazardous substance Act, B.E. 2561. (2018)

7.4 The notification of the ministry of health on transportation, transfer, destruction and inactivation of pathogens and animal toxins.

7.5 Other related notifications issued on hazardous substances.

8. Operational processes

Procedures shall be in accordance with the Pathogens and Animal toxins Act, B.E. 2558 and other related ministerial notifications. The procedures must be approved by the CICM-BCC and the TU-IBC. A person who intends to produce, import, export, sell and possess pathogens and animal toxins, must specify the pathogens and animal toxins in the pathogens list in a received certificate of notification or license of the CICM. The production, import, export, sale and possession of group 3 and group 4 pathogens, and group 2 and group 3 animal toxins are prohibited.

The use of group 3* pathogens intended to be under control can be conducted in BSL-2 laboratories enhanced with the following conditions:

1) In case of disease diagnosis without culturing pathogens, the procedure can be conducted in BSL-2 laboratories in accordance with the principles of Good Microbiological Practice.

2) In case of culturing less than 30 ml pathogens, the procedure can be conducted in BSL-2 laboratories enhanced in accordance with the Pathogens and Animal toxins Act, B.E. 2558 and the notification of the ministry of health on characteristics of the place of production or possession, and conduct of pathogens and animal toxins, B.E. 2561.

3) Culturing more than 30 ml pathogens at once is prohibited.

Projects approved by the CICM-BCC and the TU-IBC shall strictly adhere to the notification of the ministry of health on characteristics of the place of production or possession, and conduct of pathogens and animal toxins and the Pathogens and Animal toxins Act, B.E. 2558, with additional guidelines as follows:

81. Production and possession

8.1.1 Group 1 pathogens intended to be under control

8.1.1.1 Production of less than 1,000 L or 200 kg pathogens shall be done in containers with labels indicating the pathogens' information, namely their scientific name and date of production and packaging. A list and the amount of the produced pathogens shall be recorded.

8.1.1.2 Production of more than 1,000 L or 200 kg pathogens is prohibited.

8.1.2 Group 2 pathogens intended to be under control

8.1.2.1 Production of less than 10 L pathogens can be conducted. Production information, namely production amount, production number and place of storage (box, freezer, place inside freezer, etc.), shall be recorded and indicated on the container. The pathogens' information, namely their scientific name and date of production/packaging shall be labelled in English on the container. In addition, a list and the amount of the produced pathogens shall be recorded.

8.1.2.2 Production of more than 10 L pathogens is prohibited.

8.1.3 Group 3* pathogens intended to be under control

8.1.3.1 Production of less than 30 ml pathogens can be conducted. A person who intends to produce the pathogens shall notify the operator or operation personnel before the production. Production information namely, production amount, production number and place of storage (box, freezer, place inside freezer, etc.) shall be recorded and indicated on the container. The pathogens' information, namely their scientific name and date of production/packaging shall be labelled in English on the container. In addition, a list and the amount of produced pathogens shall be recorded.

8.1.4 Group 3 pathogens intended to be under control

8.1.4.1 Production of the pathogens is prohibited.

8.1.5 Production of any animal toxins is prohibited.

8.2. Import and export

8.2.1 Notify the CICM-BCC and the IBC of the recipient 7 days before transferring. The material transfer agreement must be approved by both donor and recipient before the transfer. When the transferring is done, report according to the notice of transfer, destruction and examination after destruction of pathogens and animal toxins under the notification of the ministry of health on the finishing of production, import, export, sale, transit and possession of pathogens and animal toxins B.E. 2561.

8.2.2 Group 1 pathogens intended to be under control

8.2.2.1 In case of import or export of pathogens and animal toxins, the pathogens and animal toxins shall be placed in triple layers of container as follows:

(1) Innermost container is completely closed, anti-liquid leakage and durable.

(2) Medium container is completely closed, anti-liquid leakage and durable. This container shall provide sufficient space in case of leakage from the inner container.

(3) Outermost container is made of cardboards, plastics, metals or any durable materials which can be completely closed.

8.2.2.2 Pathogen information, namely scientific name and date of production/packaging shall be labelled in English on the container.

8.2.2.3 Amount and number of produced or possessed pathogens shall be recorded.

8.2.3 Group 2 pathogens intended to be under control

8.2.3.1 Follow as described in 2.1 and 2.2 and

8.2.3.2 Arrange to have records of pathogens and animal toxins by providing information on the groups of pathogens and animal toxins and the number of used containers indicating the amount of produced pathogens/animal toxins, date of production and place of storage. The information shall be traceable.

8.2.4 Group 3* pathogens intended to be under control

8.2.4.1 Follow as described in 2.1 – 2.3 and

8.2.4.2 Arrange to have Pathogen Safety Data Sheets (PSDS) providing information of sort, source, vector, transmission, pathogenesis, treatment and preventive vaccine, personal protective equipment, first aid and methods of disposal and destruction.

8.2.5 Only group 1 animal toxins are allowed.

8.3. Transportation

Follow the notification of the ministry of health on transportation, transfer, destruction and inactivation of pathogens and animal toxins by notifying the CICM-BCC and the IBC of recipient 7 days before transfer. The material transfer agreement must be approved by both donor and recipient before the transfer.

8.3.1 Enclose pathogens declaration with the transfer.

8.3.2 Arrange to have advance appointment of transfer date between donor and recipient. The donor shall provide information on transferring pathogens, name of recipient, contact number and date and time of transfer. A list of the transferred pathogens must be specified in a certificate of notification of the donor and recipient.

8.3.3 Transfer pathogens in permitted areas only.

8.3.4 Domestic transport shall follow as described in 3.1 – 3.3 and also other related legislations.

8.3.4.1 Land transportation shall follow the criteria, procedures and conditions prescribed by laws of hazardous substance, land transportation and railway and highway management.

8.3.4.2 Water transportation shall follow the criteria, procedures and conditions prescribed by laws of hazardous substance and water transportation in the Kingdom of Thailand.

8.3.4.3 Air transportation shall follow the criteria, procedures and conditions prescribed by laws of hazardous substance and aviation.

8.3.4.4 International transport shall follow as described in 3.1 – 3.4 and other relating legislations as follows.

1) Land transportation shall follow the criteria, procedures and conditions prescribed by laws of hazardous substance of the country of origin, transit and destination.

2) Water transportation shall follow the criteria, procedures and conditions prescribed by laws of hazardous substance and shipment of the country of origin, transit and destination.

3) Air transportation shall follow the criteria, procedures and conditions prescribed by the International Air Transport Association (IATA).

8.4. Transportation of pathogens and animal toxins within the facility

8.4.1 Transportation of pathogens and animal toxins within the facility means the transportation of pathogens and animal toxins within 8th floor research laboratory, Co-operative Learning Center, Chulabhorn International College of Medicine.

8.4.2 Other transportation outside the 8th floor research laboratory, Co-operative Learning Center, Chulabhorn International College of Medicine, shall follow as described in 3.

8.4.3 Onsite transportation of pathogens and animal toxins from BSL-1 Room A to BSL-2 shall occur using a double layer container. The inner container shall be completely closed, anti-liquid leakage and durable. The outer container shall be made of cardboards, plastics, metals or any materials which are durable and which can be completely closed.

8.4.4 Transport and/or storage of pathogens and animal toxins at provided area as follows:

8.4.4.1 4-Degrees Celsius refrigerator and -20-Degrees Celsius freezer in BSL-2 Room C.

8.4.4.2 -80-Degrees Celsius freezer in BSL-1 Room A. Due to access control, a person who intends to store pathogens and animal toxins in this freezer shall notify operator or operation personnel before conducting the transportation and storage.

Institutional Biosafety Committee of Chulabhorn International College of Medicine, Thammasat University

Title:	**Destruction of pathogenic microorganisms**					**Document control**	**Page: 1 / 3**
						CICM-BCC-SA 006	**REV.01**
Prepared by	**Asst. Prof. Dr. Veerachai Thitapakorn**	**Reviewed by**	**Prof. Dr. Ratha-korn Vilaichone**	**Approved by**	**Prof. Dr. Adis Tasanarong**	**Approved date**	**9 April 2021**

1. Objective

To provide a procedure and guideline for destruction of pathogenic microorganisms

2. Scope

This procedure applied to all users who work for or are related to the Chulabhorn International College of Medicine (CICM) laboratory on the 8th floor, Co-operative Learning Centre, Thammasat University, Rangsit Campus, in response to biological spills when they occur. This procedure has been developed regarding the Pathogens and Animal Toxins Act, B.E. 2558 (2015)

3. Principle

According to the Pathogens and Animal Toxins Act, B.E. 2558 (2015) and the Notification of Ministry of Public Health: Characteristics of the place of production or possession of pathogens and animal toxins, tools, equipment, accompanying documents, labels, containers or packages for each group of pathogens and animal toxins B.E. 2561 (2018), the destruction of pathogenic microorganisms has to be conducted to ensure and prevent the accidental release of pathogens or animal toxins to users, colleagues and communities, by using proper methods of destruction which include waste and nucleic acid product management.

4. Definition and Abbreviation

4.1 CICM-BCC refers to the Institutional Biosafety Committee of the Chulabhorn International College of Medicine, Thammasat University.

4.2 TU-IBC: Institutional Biosafety Committee, Thammasat University

5 Responsible personnel

5.1 Institutional Biosafety Committee of the Chulabhorn International College of Medicine, Thammasat University

5. 2 Laboratory committee of the Chulabhorn International College of Medicine, Thammasat University

5.3 Research supporting Office

5.4 Operator of the Chulabhorn International College of Medicine, Thammasat University

5.5 Operation personnel of the Chulabhorn International College of Medicine, Thammasat University

5.6 Researchers

6. Related documents

6. 1 Notification of the Ministry of Public Health: The destruction or handover of pathogens or animal toxins to other persons receiving B.E. 2561 (2018)

6. 2 Notification of the Department of Medical Sciences: A certificate of notification for the destruction or handover of pathogens or animal toxins to other persons receiving

6. 3 A certificate of notification for destruction or handover of pathogens or animal toxins to other persons receiving from the Notification of Ministry of Public Health: Termination of the production, import, export, sale, transit or possession of pathogens or animal toxins B.E. 2561 (2018)

7. References

7.1 Pathogens and Animal Toxins Act, B.E. 2558 (2015)

7. 2 Notification of the Ministry of Public Health: Characteristics of the place of production or possession of pathogens and animal toxins of pathogens and animal toxins B.E. 2561 (2018)

7.3 Ministerial Regulation Hygienic Waste Management B.E.2545 (2002)

8. Operational processes

Destruction of pathogenic microbes can be peformed with chemicals, heat, an autoclave and by burning following the Notification of Ministry of Public Health: The destruction or handover of pathogens or animal toxins to other persons receiving B. E. 2561 (2018) and the Notification of Department of

Medical Sciences: A certificate of notification for the destruction or handover of pathogens or animal toxins to other persons receiving.

8.1 Destruction by chemicals

8.1.1 Reduce contamination or decontamination by using 0.5 – 1% of sodium hypochlorite which is prepared by dilution of a 5% sodium hypochlorite stock solution. Alternative chemical agents with scientific documentation of microbial destruction can also be used.

8.1.2 Fresh preparation for use within 1 hour.

8.1.3 Immerse for 30 minutes.

8.1.4 In case of immediate discarding, dilute the used sodium hypochlorite 10-fold: then this agent can be poured into a drainage pipe sewer.

8.1.5 Follow instructions and safety data sheets in case of alternative chemical agents.

8.2 Destruction by heating

8.2.1 This method is used for pathogenic multicellular eukaryotes only.

8.2.2 Boil at 100°C for 10 – 30 minutes.

8.3 Autoclave

8.3.1 Use an autoclave which has passed the spore test.

8.3.2 For cleaned glassware and plastic ware, sterilize by autoclaving at 121°C, 1.15 bar (or 16.9 psi) for 15 minutes.

8.3.3 For waste, sterilize by autoclaving at 134°C, 2.25 bar (or 33 psi) for 35 minutes.

8.3.4 For endospore forming or heat resistant microbes, sterilize by autoclaving at 134°C, 2.25 bar (or 33 psi) for 35 minutes.

8.4 Incineration

8.4.1 This method is used for infectious and non-infectious sharps waste. Burning at a temperature of at least 760°C and afterwards burning at 1,000°C by an outsourced company.

8.5 After finishing the process, fill a form of notification which follows the Notification of Ministry of Public Health: destruction or handover of pathogens or animal toxins to other persons receiving B.E. 2561 (2018), then notify the CICM-BCC and the TU-IBC.

Institutional Biosafety Committee of Chulabhorn International College of Medicine, Thammasat University

Title:	**Management of solid waste**					**Document control**	**page : 1 / 4**
						CICM-IBC-SA	**007 REV.01**
Prepared by	**ผศ. ดร. วีระชัย ทิตภากร**	**Reviewed by**	**Prof. Dr. Ratha-korn Vilaichone**	**Approved by**	**Prof. Dr. Adis Tasanarong**	**Approved date**	**9 April 2021**

1. Objective

To manage solid waste reliably.

2. Scope

For relevant persons to study and understand the process of waste management in the laboratories of the Chulabhorn International College of Medicine, in accordance with the Pathogen and Animal Toxins Act, 2015.

3. Principle

In order to comply with the Pathogens and Animal Toxins Act. B.E. 2558 (2015) and the characteristics of operating location, tools or equipment, safety system, and quality system in accordance with the Notification of the Ministry of Public Health prescribing the characteristics of the manufacturing location or possession and operation of pathogens and animal toxins B.E.2561 (2018). In addition, to ensure the safety of researchers, co-workers and the community. Therefore, it is necessary to manage solid waste by dividing solid waste into different types including general solid waste, infectious solid waste, chemical waste and sharp waste. The operation is not permitted in case of radioactive waste, animal carcasses or hazardous waste.

4. **Abbreviations and definitions**

4.1 CICM-IBC refers to the Institutional Biosafety Committee of Chulabhorn International College of Medicine, Thammasat University.

4.2 TU-IBC refers to the Institutional Biosafety Committee, Thammasat University.

5. Responsibilities

5. 1 Institutional Biosafety Committee of the Chulabhorn International College of Medicine, Thammasat University

5.2 Laboratory committee of the Chulabhorn International College of Medicine, Thammasat University

5.3 Research supporting Office

5.4 Operator of the Chulabhorn International College of Medicine, Thammasat University

5.5 Operation personnel of the Chulabhorn International College of Medicine, Thammasat University

5.6 Researchers

6. Related documents

6.1 Standard practice for disinfection (CICM-IBC-SA-006)

7. References

7.1 Pathogens and Animal Toxins Act, B.E. 2558 (2015)

7.2 Notification of the Ministry of Public Health prescribing the characteristics of the manufacturing location or possession and operation of pathogens and animal toxins, B.E.2561 (2018)

7.3 Ministerial regulations of the Ministry of Public Health on the elimination of infectious waste, B.E.2545 (2002)

8. Procedures

Management of general solid waste, infectious waste, sharp waste, and chemical waste

8.1 General solid waste

8.1.1 Discard the waste into general waste container provided, to a volume of no more than three-fourths of the bag.

8.1.2 Daily collect general waste and keep it at the trash area provided in order to continue elimination by Thammasat University

8.2 Infectious waste

8.2.1 Discard the waste into infectious solid waste container provided, to a volume of no more than three-fourths of the bag.

8.2.2 Daily collect infectious waste and transport by cart in a completely closed container of strong material not easily broken and not leaking. Keep it at the trash area provided.

8.2.3 Decontaminate infectious waste by autoclaving at 134 °C, 2.25 bar (33 psi) pressure for 35 minutes.

8.2.4 Eliminate sterilized infectious waste by the assigned company authorized by the ministerial regulations of the Ministry of Public Health on the elimination of infectious waste.

8.2.5 Infectious waste that has undergone decontamination with a chemical should be discarded according to the instructions provided for that chemical. To be eliminated by the assigned company.

8.3 Sharp waste

8.3.1 Discard in sharp waste container with tight closing lid, of strong material not easily broken and not leaking. Keep at the trash area provided in order to be eliminated by the assigned company.

8.4 Chemical waste

8.4.1 Discard the different types of chemicals by specifying name and volume before discarding into a chemical resistant container. Keep at the chemical waste area provided.

8.4.2 In case of unspecified type of chemical, specify name and volume before discarding in chemical resistant container. Keep at the chemical waste area provided.

8.4.3 For handling of chemical waste that is contaminated with heavy metals, proceed by bringing to the chemical waste disposal point as scheduled and assigned by research affairs. (Investigators must notify the operator before using heavy metals. This aims to determine the process of disposal of chemical waste contaminated with heavy metals.)

8.4.4 Chemical waste will be eliminated by the assigned company.

Institutional Biosafety Committee of Chulabhorn International College of Medicine, Thammasat University

Title:	**Biological spill response**					**Document control**	**Page: 1 / 7**
						CICM-IBC-SA 008	**REV.01**
Prepared by	**Asst. Prof. Dr. Veerachai Thitapakorn**	**Reviewed by**	**Prof. Dr. Ratha-korn Vilaichone**	**Approved by**	**Prof. Dr. Adis Tasanarong**	**Approved date**	**9 April 2021**

1. Objective

To provide a procedure and guideline for biological spill response

2. Scope

This procedure applies to all users who work for or are otherwise related to the Chulabhorn International College of Medicine (CICM) laboratory on the 8th floor, Co-operative Learning Centre, Thammasat University, Rangsit Campus, to respond to biological spills when they occur. This procedure has been developed regarding the Pathogens and Animal Toxins Act, B.E. 2558 (2015)

3. Principle

Regarding Pathogens and Animal Toxins Act, B.E. 2558 (2015) and Notification of Ministry of Public Health: Characteristics of the place of production or possession of pathogens and animal toxins, tools, equipment, accompanying documents, labels, containers or packages for each group of pathogens and animal toxins B.E. 2561 (2018), the response to biological spills has to be conducted to ensure and prevent the accidental release of pathogens or animal toxins to users, collogues, and communities by using a biological spill kit.

4. Abbreviations and definitions

4.1 CICM-IBC refers to the Institutional Biosafety Committee of Chulabhorn International College of Medicine, Thammasat University.

4.2 TU-IBC refers to the Institutional Biosafety Committee, Thammasat University.

5. Responsibilities

5.1 Institutional Biosafety Committee of Chulabhorn International College of Medicine, Thammasat University.

5.2 Laboratory committee of the Chulabhorn International College of Medicine, Thammasat University

5.3 Research supporting Office.

5.4 Operator of the Chulabhorn International College of Medicine, Thammasat University

5.5 Operation personnel of the Chulabhorn International College of Medicine, Thammasat University

5.6 Researchers

6. Related documents

6.1 Incident report form of unsafe biohazard from processes or procedures of produce, import, export, sale, transit, and possession of pathogens and animal toxins.

7. References

7.1 Pathogens and Animal Toxins Act, B.E. 2558 (2015)

7.2 Notification of the Ministry of Public Health: Characteristics of the place of production or possession of pathogens and animal toxins of pathogens and animal toxins B.E. 2561 (2018)

7.3 Biosafety guidelines for modern biotechnology B.E. 2559 (2016)

8. Procedures

Guideline and procedure for spill response

8.1 Spill on the floor or ground

8.1.1 Evacuate all personnel from the room and close the door.

8.1.2 Inform operator or operation personnel.

8.1.3 Wait for 30 minutes to allow aerosols to settle.

8.1.4 After 30 min, begin to clean up by spill kit, at least 2 responding persons are needed.

8.1.5 Put on personal protective equipment（PPE, *i.e.* mask, goggle, head cap, lab coat, double gloves, and shoes cover in the stated order.

8.1.6 Prepare disinfectant: pour each disinfectant powder pack into 500 ml container and mix, or prepare 0.6% sodium hypochlorite by diluting 10x the 6% sodium hypochlorite stock solution with water.

8.1.7 If there is any broken glass or sharps, use tong or dustpan and broom to remove by putting into sharps bin.

8.1.8 Cover spill with absorbent or tissue paper in a circular pattern from the outside towards the centre of the spill and cover the area at least 0.5 metre away from the last seen spill spot.

8.1.9 Gently pour appropriate amount of disinfectant onto absorbent or tissue paper from outside to inside and allow disinfectant to act for 20 min.

8.1.10 Use tong to remove absorbent or tissue papers and put into red bag no. 1

8.1.11 Repeat steps 8.1.8-8.1.10

8.1.12 Put tong into red bag no. 2

8.1.13 Take off the outer gloves and put into red bag no. 1

8.1.14 Take off the lab coat, head cap, goggles, mask and shoe covers into red bag no. 2

8.1.15 The first responding person takes off inner gloves and puts them into red bag no. 2

8.1.16 The second responding persons ties the bag and moves it to the waste area of the laboratory.

8.1.17 The second responding persons takes off inner gloves and puts them into the infectious waste bin of the laboratory.

8.1.18 Wash hands with antiseptic soap or foam before leaving the laboratory.

8.1.19 Fill in the incident report form on unsafe biohazard from processes or procedures of production, import, export, sale, transit, and possession of pathogens and animal toxins and submit to CICM-IBC.

8.2 Spill occurs inside the biosafety cabinet

In case a spill occurs inside the BSC, do NOT turn off the BSC, and follow the steps below.

8.2.1 Evacuate all personnel from the room and close the door.

8.2.2 Inform operator or operation personnel.

8.2.3 Wait for 30 minutes to allow aerosols to settle.

8.2.4 After 30 min, begin to clean up by spill kit.

8.2.5 Put on personal protective equipment (PPE), *i.e.* mask, goggles, head cap, lab coat, double gloves, and shoe covers in the stated order.

8.2.6 Prepare disinfectant: pour each disinfectant powder pack into 500 ml container and mix or prepare 0.6% sodium hypochlorite by diluting 10x the 6% sodium hypochlorite stock solution with water.

8.2.7 If there is any broken glass or sharps, use tong or dustpan and broom to remove by putting into sharps bin.

8.2.8 Cover spill with absorbent or tissue paper in a circular pattern from outside to centre of spill and cover the area at least 0.5 metre away from the last seen spill spot.

8.2.9 Gently pour proper amount of disinfectant onto absorbent or tissue papers from outside to inside and allow disinfectant to act for 20 min.

8.2.10 Use tong to remove absorbent or tissue papers and put into red bag no. 1

8.2.11 Repeat steps 8.1.8-8.1.10

8.2.12 Put tong into red bag no. 2

8.2.13 Take off the outer gloves and put into red bag no. 1

8.2.14 Leave BSC for at least 15 min after clean up

8.1.14 Take off the lab coat, head cap, goggles and mask, and put into red bag no. 3

8.2.15 Take off the shoe covers and put in red bag no. 1

8.2.16 The responding persons take off the inner gloves and put them into red bag no. 1

8.2.19 Wash hands with antiseptic soap or foam before leaving laboratory.

8.2.20 Fill the incident report form on unsafe biohazard from processes or procedures of production, import, export, sale, transit, and possession of pathogens and animal toxins, and submit to CICM-IBC.

8.3 In case spill occurs inside a centrifuge.

In case spill occurs inside a centrifuge with aerosol-tight bucket or rotor.

8.3.1 Press stop button, brake is not recommended. If there is no leakage, allow the aerosol to settle in the cup, loosen the lid, and autoclave the aerosol-tight cup. If there is spill leakage inside the centrifuge chamber, close the centrifuge cup, rotor, or lid and continue with step 8.3.2.

8.3.2 Wait for 30 minutes to allow aerosols to settle.

8.3.3 After 30 minutes, begin to clean up by spill kit.

8.3.4 Put on personal protective equipment (PPE), i.e. mask, goggles, head cap, lab coat, double gloves, and shoe covers in the stated order.

8.3.5 Turn on the BSC.

8.3.6 Remove rotor, put into BSC, open rotor lid in the BSC. If there is spill leakage in the centrifuge chamber, continue clean up in the BSL.

8.3.7 Prepare disinfectant: pour each disinfectant powder pack into 500 ml container and mix or prepare 0.6% sodium hypochlorite by diluting 10x the 6% sodium hypochlorite stock solution with water.

8.3.8 If there is any broken glass or sharps, use tong or dustpan and broom to remove by putting into sharps bin.

8.3.9 Clean up the centrifuge part or chamber with disinfectant-soaked tissue paper and allow at least 20 min, then remove the soaked paper with tong, and put into red bag no. 1

8.3.10 Repeat step 8.3.9

8.3.11 Put tong into red bag no. 2

8.3.12 Take off the outer gloves and put into red bag no. 1

8.3.13 Take off the lab coat, head cap, goggles, and mask into red bag no. 3

8.3.14 Take off the shoe covers and put into red bag no. 1

8.3.15 Tie the bag and move to waste area of the laboratory.

8.3.16 The second responding person takes off inner gloves and puts them into the infectious waste bin of the laboratory.

8.3.17 Wash hands with antiseptic soap or foam before leaving laboratory.

8.3.18 Fill out the incident report form on unsafe biohazard from processes or procedures of production, import, export, sale, transit, and possession of pathogens and animal toxins, and submit to CICM-IBC.

8.4 In case spill occurs inside the centrifuge with **non**-aerosol-tight bucket or rotor

8.4.1 Press stop button, brake is not recommended. If there is spill leakage inside the chamber of the centrifuge, close the centrifuge lid.

8.4.2 Wait for 30 minutes to allow aerosols to settle.

8.4.3 After 30 minutes, begin to clean up with spill kit.

8.4.4 Put on personal protective equipment (PPE), *i. e.* mask, goggles, head cap, lab coat, double gloves, and shoe covers in this order.

8.4.5 If centrifuge can be moved into BSC, turn on the BSC before beginning. If it cannot be moved into the BSC, continue with step 8.4.6

8.4.6 Open centrifuge lid. If there is any broken glass or sharps, use tong or dustpan and broom to remove by putting into sharps bin.

8.4.7 Prepare disinfectant: pour each disinfectant powder pack into 500 ml container and mix or prepare 0.6% sodium hypochlorite by diluting 10x the 6% sodium hypochlorite stock solution with water to 0.6%.

8.4.8 Clean up the centrifuge part or chamber with disinfectant-soaked tissue paper and allow at least 20 min, then remove the soaked paper with tong, and put into red bag no. 1

8.4.9 Repeat step 8.4.8

8.4.10 Put tong into red bag no. 2

8.4.11 Take off the outer gloves and put into red bag no. 1

8.4.12 Take off the lab coat, head cap, goggles and mask, and put into red bag no. 3

8.4.13 Take off the shoe covers and put in red bag no. 1

8.4.14 Tie the bag and move to waste area of the laboratory.

8.4.15 The second responding person takes off inner gloves and puts them into the infectious waste bin of the laboratory.

8.4.16 Wash hands with antiseptic soap or foam before leaving laboratory.

8.4.17 Fill out the incident report form on unsafe biohazard from processes or procedures of production, import, export, sale, transit, and possession of pathogens and animal toxins and submit to the CICM-IBC.

Institutional Biosafety Committee of Chulabhorn International College of Medicine, Thammasat University

Title:	Biological spill response					Document control	Page: 1 / 6
						CICM-BCC-SA 008	REV.00
Prepared by	Asst. Prof. Dr. Veerachai Thitapakorn	Reviewed by	Prof. Dr. Ratha-korn Vilaichone	Approved by	Prof. Dr. Adis Tasanarong	Approved date	9 April 2021

1. Objective

To provide a procedure and guideline for emergency responses

2. Scope

This procedure applies to all users who work for or are otherwise related to the Chulabhorn International College of Medicine (CICM) laboratory on the 8th floor, Co-operative Learning Centre, Thammasat University, Rangsit Campus, to respond to an emergency.

3. Principle

Regarding the Pathogens and Animal Toxins Act, B.E. 2558 (2015), and the Notification of Ministry of Public Health: Characteristics of the place of production or possession of pathogens and animal toxins, tools, equipment, accompanying documents, labels, containers or packages for each group of pathogens and animal toxins B.E. 2561 (2018), and the Occupational Safety, Health and Environment Act B.E. 2554, the response to an emergency has to be conducted to prevent accidents. This SOP will guide the mitigation and how to relieve harm.

4. Abbreviation and definitions

4.1 BSL2 refers to a Biosafety laboratory level 2

4.2 CICM-BCC refers to the Institutional Biosafety Committee of the Chulabhorn International College of Medicine, Thammasat University.

5. Responsibilities

5.1 Institutional Biosafety Committee of the Chulabhorn International College of Medicine, Thammasat University.

5.2 Operator of the Chulabhorn International College of Medicine, Thammasat University

5.3 Operation personnel of the Chulabhorn International College of Medicine, Thammasat University

5.4 Laboratory committee of the Chulabhorn International College of Medicine, Thammasat University

5.5 Occupational health committee of the Chulabhorn International College of Medicine, Thammasat University

5.6 Research supporting Office.

6. Related documents

None

7. References

7.1 Pathogens and Animal Toxins Act, B.E. 2558 (2015)

7.2 Notification of the Ministry of Public Health: Characteristics of the place of production or possession of pathogens and animal toxins of pathogens and animal toxins B.E. 2561 (2018)

7.3 Occupational Safety, Health and Environment Act B.E. 2554

8. Procedures

Guideline and procedures for an emergency response

8.1 Accident with chemical substances

Concentrated acids or bases are not allowed inside the BSC or BSL2, based on the elimination principle. To prepare any chemical reagent, use the fume hood. In case of an accident from chemical spills on the floor or the body, follow the steps below.

1) If eye/or face are affected, direct yourself to the eye wash and emergency shower and open the eye wash cover: water will flush automatically.
2) If body is affected, direct yourself to the emergency shower and flush the affected area by pulling the shower pull rod.
3) If injured person is unconscious or cannot move by themselves, bystanders shall put on chemical resistant gloves, chemical resistant goggles, chemical resistant mask, then

bring the mobile type of emergency shower to the injured person and use eye shower or shower to flush as much as possible. Do not use any soap or detergent or chemicals.

4) Remove lab coat or clothes contaminated with chemical substances.
5) In case of injury requiring medical treatment, call Emergency room of Thammasat hospital: 02-926-9042 to 4 to transfer the injured person.
6) Inform operator or operation personnel.
7) Respond to chemical spill by using suitable PPE and chemical spill kit. Neutralize pH by using sodium bicarbonate for spilled acids and citric acid or ascorbic acid for spilled bases.
8) Operator/operator personnel/observer/ or bystanders fill out emergency form (CICM-BCC-FA-003) and submit to the CICM-BCC.
9) CICM-BCC informs the Occupational health committee and Laboratory committee of Chulabhorn International College of Medicine, Thammasat University.
10) Operator/operator personnel/observer/ or bystanders fill out emergency form (CICM-BCC-FA-003) and submit to the CICM-BCC.
11) CICM-BCC informs Occupational health committee and Laboratory committee of Chulabhorn International College of Medicine, Thammasat University

8.2 Accident with biological substances

1) If eye/or face is affected, direct yourself to eye wash and emergency shower, and open the eye wash cover: water will flush automatically.
2) If body is affected, clean by wiping the contaminated area with 70% alcohol or skin compatible disinfectant.
3) If an injured person is unconscious or cannot move by themselves, bystanders should put on biological PPE, then bring the mobile emergency eye wash for washing eyes or

the face, or wiping the contaminated body area with 70% alcohol or skin compatible disinfectant.

4) In case of injury requiring medical treatment, call Emergency room of Thammasat hospital: 02-926-9042 to 4, to transfer the injured person.
5) Inform the operator or operation personnel.
6) Respond to biological spill by following the spill response SOP (CICM-BCC-SA-008)
7) Operator/operator personnel/observer/ or bystanders fill out emergency form (CICM-BCC-FA-003) and submit to the CICM-BCC.
8) CICM-BCC informs Occupational health committee and Laboratory committee of Chulabhorn International College of Medicine, Thammasat University.

8.3 Accident from physical or mechanical forces

8.3.1 If injured person is conscious and can move by themselves, shout for help or inform bystanders or colleagues

8.3.2 If injured person is unconscious,

1) don't move injured person
2) check for chemical spills or biological spills or wound or trauma,
3) If no spills, call Emergency room of Thammasat hospital: 02-926-9042 to 4 to transfer the injured person.
4) If spills are present, follow chemical or biological spill SOP while waiting for medical team

8.3.3 In case of chemical or biological spill, follow the chemical or biological accident SOP while waiting for the emergency team

8.3.4 For mild cases, proceed with first aid by first aid kit (stored in the front cabinet at entrance)

8.3.5 In case of injury requiring medical treatment, call Emergency room of Thammasat hospital: 02-926-9042 to 4 to transfer the injured person.

8.3.6 Inform operator or operation personnel and BCC.

8.3.7 BCC informs the Occupational health committee and Laboratory committee of Chulabhorn International College of Medicine, Thammasat University

8.4 Accident involving electricity

8.4.1 Disconnect electricity from the power source by shutting off the main circuit breaker located in the anteroom

8.4.2 Call Emergency room of Thammasat hospital: 02-926-9042 to 4 to transfer any injured person.

8.4.3 Check for chemical or biological spills or wound or trauma

8.4.4 If spills are present, follow the chemical or biological spill SOP while waiting for the medical team

8.4.5 Inform operator or operation personnel and BCC

8.4.6 CICM-BCC informs the Occupational health committee and Laboratory committee of the Chulabhorn International College of Medicine, Thammasat University

8.5 Emergency involving fire

8.5.1 Bystanders in BSL2

1) Shut off the main circuit breaker located in the anteroom, if possible
2) Extinguish fire by spraying at the base of the fire with a fire extinguisher
3) If fire is inextinguishable, move to corridor or break the glass partition wall of BSL1 room, corridor, or terrace, in order to move to accessible fire exit
4) When safe from fire, inform security team by calling 02-564-4407
5) If a person is injured, call Emergency room of Thammasat hospital: 02-926-9042 to 4 to transfer the injured person
6) Follow the fire drill emergency response

8.5.2 Colleagues or bystanders at corridor or BSL1

1) Extinguish fire with fire extinguisher located in the corridor or BSL1 area, by spraying at the base of the fire
2) If fire is inextinguishable, move to accessible fire exit
3) Do not move to BSL2
4) When safe from fire, inform security team by calling 02-564-4407
5) If a person is injured, call Emergency room of Thammasat hospital: 02-926-9042 to 4 to transfer the injured person
6) Follow the fire drill emergency response