



## STANDARD OPERATING PROCEDURE

### TRANSPORTATION OF RECOMBINANT NUCLEIC ACID (VCUSM14P)

Standard Operating Procedure No.	1
Revision No:	1
Original Date of Issue:	30 September 2022
Revision Date:	31 March 2023
Revised by:	Dr Maryam Azlan
Approved by:	Dr Maryam Azlan

**Background:** The content of this SOP is based on requirements established by the following standards:

- NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines), National Institutes of Health
- Biosafety in Microbiological and Biomedical Laboratories (BMBL), Centers for Disease Control and National Institutes of Health
- Biosafety Guidelines Contained Use Activity of Living Modified Organism Section 6.2, Department of Biosafety Malaysia

**Purpose:** To provide instruction on transportation of recombinant nucleic acid (VCUSM14P)

To provide emergency responses, if traffic collision including car accident occur during transportation of the LMO.

Procedures:

<p><b>Hazard Identification and Risk of Exposure to the Hazards:</b></p>	<p>Exposure to VCUSM14P</p>
<p><b>Transportation</b></p>	<p><b>Responsibilities:</b></p> <ul style="list-style-type: none"> <li>• All personnel must be deemed well prepared and well trained prior to working on any of the above material. Subject to refresher training by supervisor every six months or when deemed necessary.</li> <li>• For the movement and transport of LMO and related materials (including import and export), the following shall apply:</li> <li>• The regulatory authorities (IBC and NBB) shall be notified using the relevant forms.</li> <li>• LMO being transferred should be packaged in secure, unbreakable and leak-proof secondary containers capable of preventing material loss during transportation. LMO should be kept separate from other materials. Outer packaging, labelling and documentation will be attached to the package before removal off-site.</li> <li>• Disinfectants (1:10 sodium hypochlorite) and absorbent paper towels/cloths must be prepared in the vehicle should any leakage or spill occur.</li> <li>• All container both primary and secondary container should be unbreakable, withstand the temperature to which they are subjected, and sealed. The containers both primary and secondary MUST be able to remain closed and sealed during all reasonably expected conditions of transport and storage, including traffic collision (e.g. car accident).</li> </ul> <p><b>Procedures:</b></p>

Appendix 1

	<ul style="list-style-type: none"><li>• Place the cultures of microorganism or cell lines in a primary container containing VCUSM14P that is secure closed-watertight and sift-proof and unbreakable.</li><li>• Place the primary container containing VCUSM14P within a sealed and leakproof secondary container, which is resistant to breakage or water damage.</li><li>• Place padding material such as paper pads at the top, bottom and sides between primary and secondary containers to prevent breakage of the primary container during transport. Place padding material in between primary and secondary container to absorb impact from shocks and vibrations during transportation.</li><li>• Include sufficient absorbent material (e.g. paper towel) inside both primary and secondary containers, to absorb any leakage that must only occur within the containers.</li><li>• Prior to transport and after transport, all containers including external surface of the primary and secondary container must be decontaminated using 70% ethanol.</li><li>• For local surface transport, enclose each set of primary and secondary containers in an outer container made of corrugated fiberboard, corrugated cardboard, wood or other material of equivalent strength. For air transport and shipment, the primary, secondary and outer container should follow International Air Transport Association (IATA) requirements (<a href="http://www.iata.org/">http://www.iata.org/</a>).</li></ul>
--	--

<p><b>Emergency responses during transportation</b></p>	<p><b>Responsibilities:</b></p> <p>Access to LMOs must be restricted, by any means that is effective to only persons approved by the IBC to handle the LMOs.</p> <ul style="list-style-type: none"><li>• This can be achieved by keeping containers in a locked area until collection, or by an approved person accompanying LMOs at all times during transport.</li></ul> <p><b>Procedure:</b></p> <ul style="list-style-type: none"><li>• All personnel in charge of transporting the LMOs must inform PI (Dr Maryam Azlan) immediately at 09-7677836 or 013-5265893, prior to transportation of LMOs. The personnel need to activate a GPS tracker using any possible reliable apps (including WhatsApp live location) for PI to keep track on the transportation status and live location.</li></ul> <p>If traffic collision occurs, and if personnel is still unharmed, immediately contact Malaysian Emergency Response Services 999 and update the situation to PI.</p> <ul style="list-style-type: none"><li>• Should any leak or spill of LMO occur in the vehicle, with the gloves on, wipe up spills with a disinfectant-soaked paper towel and clean the surface with a suitable cloth.</li></ul>
---	---

Related Forms and documentation:

- Notification of Export (Form F)  
<https://bit.ly/3Ki7lX>

Records:

- Personnel will record transport pertaining to LMO.



## STANDARD OPERATING PROCEDURE

### DECONTAMINATION AND DISPOSAL PROCEDURE FOR BIOHAZARDOUS MATERIAL, INCLUDING RECOMBINANT NUCLEIC ACIDS AT SCHOOL OF HEALTH SCIENCES LABORATORIES

Standard Operating Procedure No.	2
Revision No:	1
Original Date of Issue:	30 September 2022
Revision Date:	20 May 2023
Revised by:	Dr Maryam Azlan
Approved by:	Dr Maryam Azlan

**Background:** The content of this SOP is based on requirements established by the following standards:

- NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines), National Institutes of Health
- Biosafety in Microbiological and Biomedical Laboratories (BMBL), Centers for Disease Control and National Institutes of Health
- WHO Laboratory Biosafety Manual (4<sup>th</sup> ed.) Decontamination and waste management Section 3.5
- Standard Operating Procedures for Animal Waste Disposal, University of Montana  
<https://www.umt.edu/laboratory-animal-resources/sops/sop-waste-disposal.php>

**Purpose:** To provide instruction on decontamination and disposal procedure for biohazardous material, including recombinant nucleic acids

**Procedures:**

<b>Hazard Identification and Risk of Exposure to the Hazards:</b>	Exposure to potentially infectious materials including recombinant nucleic acid (VCUSM14P)
<b>General Safety Procedure</b>	1. Wear Personal Protective Equipment (PPE): Lab coat that is only specifically used in the BSL2, double glove, and protective eye wear.

	<ol style="list-style-type: none"> <li>2. <u>No usage of sharps</u> during the transfection/transduction activities in the cell culture room.</li> <li>3. Restricted access to the cell culture room.</li> <li>4. Clean and decontaminate work surfaces, equipment, and tools before and after use with an appropriate disinfectant recommended for LMOs.</li> <li>5. Follow manufacturer's instructions for the preparation and application of the disinfectant.</li> <li>6. Pay special attention to high-touch areas and equipment that comes into direct contact with LMOs.</li> <li>7. Use disposable absorbent materials for wiping surfaces, followed by proper disposal.</li> </ol>
<p><b>Waste handling and disposal</b></p>	<p><b>1. Decontamination procedures</b></p> <p><u>1.1 Liquid decontamination procedure:</u></p> <ol style="list-style-type: none"> <li>a) Use tissue paper to absorb liquid contaminant.</li> <li>b) Clean the contaminated area with 10% bleach (1:9 v/v) solution.</li> <li>c) Discard all contaminated tissue paper in double bagged biohazard waste bin.</li> </ol> <p><u>1.2 Equipment decontamination procedure:</u></p> <ol style="list-style-type: none"> <li>a) Use tissue paper to absorb liquid contaminant.</li> <li>b) Remove any part that is possible to be removed.</li> <li>c) Clean the contaminated area with 10% bleach (1:9 v/v) solution.</li> <li>d) Allow disinfectant 30 minutes of contact time before removal. Rinse with water to remove remaining bleach that may pit or etch work surfaces &amp; equipment.</li> <li>e) Finally, rinse with 70% ethanol.</li> </ol>

- f) Discard all contaminated tissue paper in double bagged biohazard waste bin.

1.3 Handling of reusable glass wares:

- a) Disinfect reusable glassware by soaking in 10% bleach for 30 minutes.
- b) Wash the glassware with detergent and copious amounts of water.
- c) Autoclave the glassware.

**2. Waste handling procedures**

2.1 Liquid waste: bacteria growth medium, cell culture medium, genetically modified cell line:

- a) Prepare bleach/disinfectant in the plastic container and place in the biosafety cabinet. The stock solution for bleach/disinfectant should be regularly maintained in each laboratory.
- b) Discard liquid waste in the plastic container, up until three-quarters full.
- c) Soak the liquid waste in final volume of 10% bleach for 30 minutes.
- d) Discard the decontaminated liquid waste down the sink followed by copious amounts of water.

2.2 Solid waste: Consumables containing bacterial cells (culture plate, cell culture flask, centrifuge tube):

- a) Properly recapped all consumables.
- b) Discard all consumables in double bagged biohazard waste bin.
- c) Autoclave the biohazard plastic bag.
- d) Place the material in transfer container before transport to the allocated place designated by the institution.

2.3 Solid waste: Consumables containing bacterial cells (pipette tips, serological pipette)

- a) Discard all consumables in the puncture-resistant container, up until three-quarters full.
- b) Properly close the container and transport to the allocated place designated by the institution.

2.4 Animal waste:

- a) All mice will be sacrificed at the end of the pre-immunization period. All wastes potentially containing LMO including mice droppings and beddings will be separated from other animals.
- b) All non-hazardous waste is placed into black trash can bags that are a minimum of 3 mm thick (under IACUC approved guidelines).
- c) The trash bags are taken to the dumpster outside the ARASC building to be delivered to the local landfill.
- d) Hazardous chemical or biological waste will be stored in plastic bags in a designated freezer (HS 015A and SB 028) and will be picked up for medical waste disposal by Radicare. This includes carcasses of animals immunized with LMOs, as well as carcasses of animals used in studies involving hazardous chemicals or hazardous biologicals.

2.5 Autoclaving

- a) All wastes contaminated with the LMO must be sent for autoclave to Unit Pengurusan Makmal Sains (UPMS) at School of Health Sciences (PPSK).
- b) All autoclave activity is performed at 121°C for 20 minutes according to standard protocol prepared by PPSK.



## Appendix 2

--	--

### Related Forms and documentation:

- Waste Disposal Form  
<http://www.ppsk.usm.my:86/upms/repository.nsf/sisamenu?OpenForm>

### Records:

- The Science Lab Management Unit (UPMS) will record all waste disposals pertaining to LMO.



## STANDARD OPERATING PROCEDURE

### EMERGENCY RESPONSE PLAN FOR RECOMBINANT NUCLEIC ACID (VCUSM14P)

Standard Operating Procedure No.	3
Revision No:	0
Original Date of Issue:	30 September 2022
Revision Date:	0
Revised by:	-
Approved by:	Dr Maryam Azlan

**Background:** The content of this SOP is based on requirements established by the following standards:

- NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines), National Institutes of Health
- Biosafety in Microbiological and Biomedical Laboratories (BMBL), Centers for Disease Control and National Institutes of Health
- Biosafety Guidelines Contained Use Activity of Living Modified Organism Section 6.2, Department of Biosafety Malaysia

**Purpose:** To provide instruction on emergency response plan for recombinant nucleic acid (VCUSM14P)

**Procedures:**

<b>Hazard Identification and Risk of Exposure to the Hazards:</b>	Exposure to VCUSM14P
<b>Responsibilities</b>	All personnel working with and responding to incidents involving recombinant or synthetic nucleic acids are responsible for adherence to this policy.

	<p>All personnel (with the exception of the supervisor) working with any of the above-mentioned material do not have any authority to hand out the material to anyone whose names are not listed under each project, nor are they authorized to train anyone.</p> <p>All personnel must be deemed well prepared and well trained prior to working on any of the above material. Subject to refresher training by supervisor every six months or when deemed necessary.</p>
<p><b>Personnel Exposure Procedures</b></p>	<p>Exposure:</p> <ul style="list-style-type: none"> <li>• Broken glass container and/or splashes of VCUSM14P to mucous membranes (eyes, nose, mouth)</li> </ul> <p>Immediate response:</p> <ul style="list-style-type: none"> <li>• Skin exposure: Immediately remove contaminated personal protective equipment or clothing. Decontaminate the area with an iodine solution or antibacterial soap and copious water for 15 minutes.</li> <li>• Eye exposure: Flush the eye with water for at least 15 minutes at an eyewash station.</li> <li>• Tongs or forceps will be used to pick up broken glass or sharps (if applicable) and place in a puncture-resistant container.</li> <li>• The soaked paper towels will be removed with a gloved hand and disposed in a plastic bag.</li> </ul> <p>Notify Biosafety Officer and/or PI or Supervisor:</p> <ul style="list-style-type: none"> <li>• <b>Notify Biosafety Officer (Puan Siti Mahirah Yusuf), 09-7677801 or 012-9626604 or PI (Dr Maryam Azlan) immediately, 09-7677836 or 013-5265893.</b></li> <li>• If Biosafety Officer/PI/supervisor is not available, immediately proceed to the next step.</li> </ul> <p>Medical treatment:</p> <ul style="list-style-type: none"> <li>• During <b>office hours</b>, report to security officer (<b>Pegawai Keselamatan PPSK) 09-7671370</b></li> <li>• After <b>office hours and weekends</b>, report to security officer (<b>Pegawai Keselamatan Kampus Kesehatan) 09-7675999</b></li> </ul>

<p><b>Unintentional Environmental Release Procedures</b></p>	<p>Case examples:</p> <ul style="list-style-type: none"> <li>• Significant spill or release of any rNA molecules outside of containment equipment</li> <li>• Significant spill or release of VCUSM14P outside of containment equipment</li> <li>• Theft, loss, or release of any rNA molecules into the environment, including escape or improper disposal of a transgenic cells</li> </ul> <p>Immediate response:</p> <ul style="list-style-type: none"> <li>• Small spills: Wipe up spills with a disinfectant-soaked paper towel and clean the surface with a suitable.</li> <li>• Large spills: First, warn everyone to evacuate that area. Remove contaminated clothing and items in vicinity of spills, place in a bag for decontamination by disinfecting, autoclaving or incinerating (if need be); if footwear has been contaminated, take care not to track contamination into clean areas before removing; wash hands thoroughly. Seek assistance from the Biosafety Officer if needed. Designate warning signs to the area to prevent others from entering.</li> </ul>
--	--

Related Forms and documentation:

- USM Incident and Accident Reporting SOP  
<http://web.usm.my/chem/osh/Borang%20Laporan%20Siasatan%20Kemalangan/ProAduan.pdf>
- Incident Reporting Form (IBC Annex 3)  
<https://www.biosafety.gov.my/en/perkhidmatan/tadbir-urus-ibc/senarai-borang-berkaitan-ibc/>
- Institutional Biosafety Committee Occupational Disease/ Exposure Investigation Form (IBC Annex 4)  
<https://www.biosafety.gov.my/en/perkhidmatan/tadbir-urus-ibc/senarai-borang-berkaitan-ibc/>

Records:

- Biosafety Science Officer will record any activities/incidents pertaining to LMO.



## STANDARD OPERATING PROCEDURE

### TRANSPORTATION OF RECOMBINANT PROTEIN (WITHIN USM)

Standard Operating Procedure No.	1
Revision No:	1
Original Date of Issue:	2 January 2023
Revision Date:	7 March 2023
Revised by:	Amiratul Aifa binti Mohamad Asri
Approved by:	Assoc. Prof. Dr. Rapeah Suppian

**Background:** The content of this SOP is based on requirements established by the following standards:

- NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines), National Institutes of Health
- Biosafety in Microbiological and Biomedical Laboratories (BMBL), Centers for Disease Control and National Institutes of Health
- Biosafety Guidelines Contained Use Activity of Living Modified Organism Section 6.2, Department of Biosafety Malaysia

**Purpose:**

- 1) To provide instruction on transfer of recombinant protein (rp) (recombinant adeno-associated viral vector) from one laboratory to another within the same building.
- 2) To provide guidance on emergency responses during transportation of rp (eg: spill).

Appendix 1

Procedures:

<p><b>Hazard Identification and Risk of Exposure to the Hazards:</b></p>	<p>Exposure to recombinant adeno-associated viral vector.</p>
<p><b>Transfer</b></p>	<p><b>Responsibilities:</b></p> <ul style="list-style-type: none"> <li>● All personnel must be deemed well prepared and well trained prior to working on any of the above material. Subject to refresher training by supervisor every six months or when deemed necessary.</li> <li>● Access to recombinant proteins must be restricted, by any means that is effective to only persons approved by the IBC to handle the recombinant proteins. This can be achieved by keeping containers in a locked area until collection, or by an approved person accompanying recombinant proteins at all times during transfer/transport between the premises (as stated in Form E).</li> <li>● All personnel in charge of transferring the recombinant proteins must immediately inform <b>PI (Assoc. Prof. Dr Rapeah Suppian) at 09-7677782 or 013-9105728</b>, prior to transfer of recombinant proteins.</li> </ul> <p><b>Transferring the recombinant protein (rp)</b></p> <ol style="list-style-type: none"> <li>1. Wrap the vial/petri dish lid containing the rp are wrapped securely with parafilm to ensure that it is leak-proof.</li> <li>2. Prepare a leak-proof container (eg: lockable ice box). Label the icebox with the details of the rp (eg: Person-in-charge, phone number and biohazard label).</li> <li>3. Disinfect the container with 70% alcohol to ensure</li> <li>4. Fill in the container with ice and place the vial/petri dish containing the rp. If the rp is in a vial, make sure that the vial is placed upright in the ice.</li> <li>5. Close the container and lock to ensure that it is leak-proof.</li> <li>6. Transport the rp to th destination.</li> <li>7. Record the movement/transfer of the rp in the inventory log.</li> </ol>
<p><b>Emergency responses during transfer</b></p>	<p><b>Managing spills</b></p> <p><i>Small spills</i></p> <ol style="list-style-type: none"> <li>1. Alert other people around the spill location.</li> <li>2. Put on appropriate PPE (eg: gloves and goggles).</li> <li>3. Wipe up spills with sufficient absorbent material (eg: paper towel) soaked in disinfectant (1:10 sodium hypochlorite/bleach).</li> <li>4. Clean the surface with suitable cloth.</li> <li>5. Record the incident in the incident reporting form report to the PI and Biosafety Officer.</li> </ol> <p><i>Large spills</i></p> <ol style="list-style-type: none"> <li>1. Warn everyone to evacuate the area.</li> </ol>

## Appendix 1

	<ol style="list-style-type: none"><li>2. Remove contaminated clothing and items in the vicinity of spills.</li><li>3. Place in a bag for decontamination by disinfecting, autoclaving or incinerating (if need be).</li><li>4. If footwear has been contaminated, take care not to track contamination into clean areas before removing</li><li>5. Clean the surface with suitable cloth.</li><li>6. Designate warning signs to prevent others from entering.</li><li>7. Seek assistance from the Biosafety Officer if needed.</li><li>8. Record the incident in the incident reporting form and report to the PI and Biosafety Officer.</li></ol>
--	--

### Related Forms and documentation:

- Incident Reporting Form (Annex 3)  
[https://www.biosafety.gov.my/wp-content/uploads/2021/08/IBC-ANNEX-3\\_rev2020.docx](https://www.biosafety.gov.my/wp-content/uploads/2021/08/IBC-ANNEX-3_rev2020.docx)
- Occupational Disease/Exposure Investigation Form (Annex 4)  
[https://www.biosafety.gov.my/wp-content/uploads/2021/08/IBC-ANNEX-4\\_rev2020.docx](https://www.biosafety.gov.my/wp-content/uploads/2021/08/IBC-ANNEX-4_rev2020.docx)

### Records:

- Personnel will record transport pertaining to the recombinant protein in the Inventory Log provided.



## STANDARD OPERATING PROCEDURE

### DECONTAMINATION AND DISPOSAL PROCEDURE FOR BIOHAZARDOUS MATERIAL, INCLUDING RECOMBINANT PROTEIN AT SCHOOL OF HEALTH SCIENCES LABORATORIES

Standard Operating Procedure No.	2
Revision No:	0
Original Date of Issue:	2 January 2023
Revision Date:	0
Revised by:	0
Approved by:	Assoc. Prof. Dr. Rapeah Suppian

**Background:** The content of this SOP is based on requirements established by the following standards:

- NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines), National Institutes of Health
- Biosafety in Microbiological and Biomedical Laboratories (BMBL), Centers for Disease Control and National Institutes of Health
- WHO Laboratory Biosafety Manual (4<sup>th</sup> ed.) Decontamination and waste management Section 3.5

**Purpose:** To provide instruction on decontamination and disposal procedure for biohazardous material, including recombinant protein.



Procedures:

<p><b>Hazard Identification and Risk of Exposure to the Hazards:</b></p>	<p>Exposure to potentially infectious materials including recombinant protein (recombinant adeno-associated viral vector)</p>
<p><b>General Safety Procedure</b></p>	<p>Wear Personal Protective Equipment (PPE): Disposable lab gown that is only specifically used in the BSL2, disposable gloves and face protection when splashes, sprays or aerosols can be expected.</p> <p><b>No usage of sharps</b> during the transfection/transduction activities in the cell culture room.          Restricted access to the cell culture room.</p> <p>Liquid decontamination procedure:</p> <ol style="list-style-type: none"> <li>1. Use tissue paper to absorb liquid contaminant.</li> <li>2. Clean the contaminated area with 10% bleach (1:9 v/v) solution.</li> <li>3. Discard all contaminated tissue paper in double bagged biohazard waste bin.</li> </ol> <p>Equipment decontamination procedure:</p> <ol style="list-style-type: none"> <li>1. Use tissue paper to absorb liquid contaminant.</li> <li>2. Remove any part that is possible to be removed.</li> <li>3. Clean the contaminated area with 10% bleach (1:9 v/v) solution.</li> <li>4. Allow disinfectant 30 minutes of contact time before removal. Rinse with water to remove remaining bleach that may pit or etch work surfaces &amp; equipment.</li> <li>5. Finally, rinse with 70% ethanol.</li> <li>6. Discard all contaminated tissue paper in double bagged biohazard waste bin.</li> </ol> <p>Handling of reusable glasswares:</p> <ol style="list-style-type: none"> <li>1. Disinfect reusable glassware by soaking in 10% bleach for 30 minutes.</li> <li>2. Wash the glassware with detergent and copious amounts of water.</li> <li>3. Autoclave the glassware.</li> </ol>

<p><b>Waste handling and disposal</b></p>	<p>Solid waste: Consumables containing viral/bacterial cells/recombinant protein (culture plate, cell culture flask, centrifuge tube):</p> <ol style="list-style-type: none"> <li>1. Properly recap all consumables.</li> <li>2. Discard all consumables in double bagged biohazard waste bin.</li> <li>3. Autoclave the biohazard plastic bag.</li> <li>4. Place the material in transfer container before transport to the allocated place designated by the institution.</li> </ol> <p>Solid waste: Consumables containing bacterial cells (pipette tips, serological pipette)</p> <ol style="list-style-type: none"> <li>1. Discard all consumables in the puncture-resistant container, up until three-quarters full.</li> <li>2. Properly close the container and transport to the allocated place designated by the institution.</li> </ol> <p>Liquid waste: 293AAV growth medium, cell culture medium, genetically modified cell line</p> <ol style="list-style-type: none"> <li>1. Prepare bleach/disinfectant in the plastic container and place in the biosafety cabinet. The stock solution for bleach/disinfectant should be regularly maintained in each laboratory.</li> <li>2. Discard liquid waste in the plastic container, up until three-quarters full.</li> <li>3. Soak the liquid waste in final volume of 10% bleach for 30 minutes.</li> <li>4. Discard the decontaminated liquid waste down the sink followed by copious amounts of water.</li> </ol> <p>All autoclave activity is performed at 121°C for 20 minutes according to standard protocol.</p>
---	---

Related Forms and documentation:

- Waste Disposal Form  
<http://www.ppsk.usm.my:86/upms/repository.nsf/sisamenu?OpenForm> (can only be accessed with USM local area network)

Records:

- The Science Lab Management Unit (UPMS) will record all waste disposals pertaining to recombinant protein.



## STANDARD OPERATING PROCEDURE EMERGENCY RESPONSE PLAN DURING TRANSPORTATION AND HANDLING OF THE RECOMBINANT PROTEIN

Standard Operating Procedure No.	3
Revision No:	1
Original Date of Issue:	2 January 2023
Revision Date:	7 March 2023
Revised by:	Amiratul Aifa binti Mohamad Asri
Approved by:	Assoc. Prof. Dr. Rapeah Suppian

**Background:** The content of this SOP is based on requirements established by the following standards:

- NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines), National Institutes of Health
- Biosafety in Microbiological and Biomedical Laboratories (BMBL), Centers for Disease Control and National Institutes of Health
- Biosafety Guidelines Contained Use Activity of Living Modified Organism Section 6.2, Department of Biosafety Malaysia

**Purpose:** To provide instruction on emergency response plan when handling the recombinant protein.

**Procedures:**

<b>Hazard Identification and Risk of Exposure to the Hazards:</b>	Exposure to recombinant protein (recombinant adeno-associated viral vector)
<b>Responsibilities</b>	All personnel working with and responding to incidents involving recombinant or synthetic protein are responsible for adherence to this policy.

	<p>All personnel (with the exception of the supervisor) working with any of the above-mentioned material do not have any authority to hand out the material to anyone whose names are not listed under each project, nor are they authorized to train anyone.</p> <p>All personnel must be deemed well prepared and well trained prior to working on any of the above material. Subject to refresher training by supervisor every six months or when deemed necessary.</p>
<p><b>Personnel Exposure Procedures</b></p>	<p><i>Case example: Broken glass container and/or splashes of rp to mucous membranes (eyes, nose, mouth)</i></p> <p><i>Immediate Response:</i></p> <p><u><i>Skin Exposure</i></u></p> <ol style="list-style-type: none"> <li>1. Immediately remove contaminated personal protective equipment or clothing.</li> <li>2. Wash the exposed area with copious amounts of water and soap for 1 minute.</li> <li>3. Obtain medical attention if necessary.</li> <li>4. Report the incident to the supervisor and Biosafety Officer.</li> </ol> <p><u><i>Eye Exposure</i></u></p> <ol style="list-style-type: none"> <li>1. Immediately rinse the eyeball and inner surface of the eyelid with water continuously for 15 minutes.</li> <li>2. Forcibly hold the eye open to ensure effective wash behind eyelids.</li> <li>3. Obtain medical attention.</li> <li>4. Report the incident to the supervisor and Biosafety Officer.</li> </ol> <p><u><i>Managing Broken Glass</i></u></p> <ol style="list-style-type: none"> <li>1. Tongs or forceps will be used to pick up broken glass or sharps (if applicable) and place in a puncture-resistant container.</li> </ol>

	<p>2. The soaked paper towels will be removed with a gloved hand and disposed of in a plastic bag.</p> <p><i>Immediately notify Biosafety Officer and/or PI or Supervisor:</i></p> <p><b>Biosafety Officer for School of Health Sciences</b>  Name: <b>Puan Siti Mahirah Yusuf</b>  Contact Number: <b>09-7677801</b> or <b>012-9626604</b></p> <p><b>Principal Investigator</b>  Name: <b>Assoc. Prof. Dr Rapeah Suppian</b>  Contact Number: <b>09-7677782</b> or <b>013-9105728</b></p> <p>Additionally, the incident must also be notified to IBC USM.</p> <p><i>If Biosafety Officer/PI/supervisor is not available, immediately proceed to the next step.</i></p> <p><b>Medical treatment:</b></p> <p>During <b>office hours</b>, report to security officer (<b>Pegawai Keselamatan PPSK</b>):  Contact Number: <b>09-7671370</b></p> <p><b>After office hours and weekends</b>, report to security officer (<b>Pegawai Keselamatan Kampus Kesehatan</b>)  Contact Number: <b>09-7675999</b></p>
<p><b>Unintentional Environmental Release Procedures</b></p>	<p><i>Case examples:</i></p> <ol style="list-style-type: none"> <li>1. Significant spill or release of any recombinant protein outside of containment equipment</li> <li>2. Significant spill or release of recombinant adeno-associated viral vector outside of containment equipment</li> </ol>

	<p><i>Immediate Response:</i></p> <p><i>Small spills</i></p> <ol style="list-style-type: none"><li>1. Alert other people around the spill location.</li><li>2. Put on appropriate PPE (eg: gloves and goggles).</li><li>3. Wipe up spills with sufficient absorbent material (eg: paper towel) soaked in disinfectant (1:10 sodium hypochlorite/bleach).</li><li>4. Clean the surface with suitable cloth.</li><li>5. Record the incident in the incident reporting form and report the incident to PI and Biosafety Officer.</li></ol> <p><i>Large spills</i></p> <ol style="list-style-type: none"><li>1. Warn everyone to evacuate the area.</li><li>2. Remove contaminated clothing and items in the vicinity of spills.</li><li>3. Place in a bag for decontamination by disinfecting, autoclaving or incinerating (if need be).</li><li>4. If footwear has been contaminated, take care not to track contamination into clean areas before removing</li><li>5. Clean the surface with suitable cloth.</li><li>6. Designate warning signs to prevent others from entering.</li><li>7. Seek assistance from the Biosafety Officer if needed.</li><li>8. Record the incident in the incident reporting form and report to the PI and Biosafety Officer.</li></ol>
--	--

Related Forms and documentation:

- USM Incident and Accident Reporting SOP  
<http://web.usm.my/chem/osh/Borang%20Laporan%20Siasatan%20Kemalangan/ProAduan.pdf>
- Incident Reporting Form (IBC Annex 3)

## Appendix 3

<https://www.biosafety.gov.my/en/perkhidmatan/tadbir-urus-ibc/senarai-borang-berkaitan-ibc/>

- Institutional Biosafety Committee Occupational Disease/ Exposure Investigation Form (IBC Annex 4)

<https://www.biosafety.gov.my/en/perkhidmatan/tadbir-urus-ibc/senarai-borang-berkaitan-ibc/>

### Records:

- Biosafety Science Officer will record any activities/incidents pertaining to recombinant protein.