



Flinders University

Standard Operating Procedure Transport of Genetically Modified Microorganisms

SOP Number:	SOP prepared by:	Date created:
IBC_SOP_3	Jess Hall	December 2015
IBC approval date:	Contact:	Review date:
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1. Relevant Legislation and Policies

- *Gene Technology Act 2000*
- *Gene Technology Regulations 2011*
- *Guidelines for the Transport, Storage and Disposal of GMOs*
- *Australian Code for the Care and Use of Animals for Scientific Purposes, 8th edn.*
- *Animal Welfare Act 1985*
- *Animal Welfare Regulations 2012*
- *Commonwealth Quarantine Act 1908*
- *Flinders University Policy on Research Practice 2001*

2. Biosafety & Animal Welfare Policy

- Flinders University is accredited by the Office of the Gene Technology Regulator (OGTR) under Section 92 of the *Gene Technology Act 2000* (the *Act*). Any person wishing to undertake work involving gene technology and/or Genetically Modified Organisms (GMOs) at the University must seek and receive approval from the Flinders University Institutional Biosafety Committee (IBC) before commencing work. All work involving GMOs must be conducted in accordance with the *Act*, the *Gene Technology Regulations 2011* (the *Regulations*) and associated guidelines. Application forms can be found on the Flinders University biosafety website:
<http://www.flinders.edu.au/research/researcher-support/ebi/biosafety/resources/forms.cfm>
- All staff and students involved in research with GMOs must attend Biosafety Training Day once every three years, or when the *Gene Technology Act* and *Regulations* are updated.

Research involving animals:

- The University holds a licence for the use of animals for teaching and research purposes. To satisfy the conditions of the licence, anyone wishing to undertake teaching and research using animals must submit a proposal to the Animal Welfare Committee (AWC). No work with animals may commence until written approval has been received from the AWC. Application forms can be found on the Flinders University Animal Ethics website:
<http://www.flinders.edu.au/research/researcher-support/ebi/animal-ethics/resources/forms.cfm>
- All staff and students involved in animal research must also complete Animal Ethics Online Training.

3. Risk Assessment

Refer to Risk Assessments (RA), Safe Work Method Statements (SWMS) and Safety Data Sheets (SDS) for substances, processes and plant equipment where appropriate. All Notifiable Low Risk

Dealings (NLRDs) must have an accompanying risk assessment approved by the Institutional Biosafety Committee.

4. Before Work Commences

- a) Ensure that you have approval to transport GMOs as part of your approved IBC project (see section 5 below for activities considered to be 'transport').
- b) RA, SWMS and SDS – ensure you have read and understood for all substances, processes and plant equipment being used.
- c) Ensure that you are aware of the locations of the following in the work area(s):
 - Spill kit
 - Fire extinguisher
 - Eye wash and safety shower
 - Exits
 - Required PPE
 - Unintentional release flowchart (in PC facilities)

5. Transport Requiring Approval Under the Gene Technology Act 2001

As defined in the OGTR Guidelines for the Transport, Storage and Disposal of GMOs, transport includes ALL of the following:

- movement of GMOs from one certified physical containment (PC) facility to another;
- movement of GMOs between a certified PC facility and a storage location outside of an authorised PC facility;
- movement of GMOs imported into Australia from the Australian border to: a certified PC facility; storage outside of a certified PC facility; a point of export from Australia; or to a place where the GMOs are to be decontaminated or disposed of;
- movement of GMOs to be exported from Australia from the time that the GMOs leave a certified PC facility or a storage location outside of an authorised PC facility until the GMOs have left Australia;
- movement of GMOs between a place of storage to another place of storage;
- movement of GMOs between any points specified in a licence;
- movement of GMOs from any point specified in a licence to an authorised PC facility; and
- movement of GMOs or waste containing GMOs from a certified PC facility, or from storage outside of a certified PC facility, to a place where the GMOs are to be decontaminated or disposed of (e.g. to an autoclave or incinerator).

6. General Requirements for Transport of GMOs

The following requirements apply to the transport of GM microorganisms (including GM/non-GM plants or GM/non-GM animals containing GM microorganisms).

NOTE: Consideration should be given to alternatives to transporting animals or plants that host pathogenic GM microorganisms, such as transporting cultures of the microorganisms for later inoculation.

PC1 and PC2 GMOs may only be transported to another facility of the same containment level or higher, or to a locked storage facility outside of a certified facility, or to a place for decontamination/destruction. Live PC1 and PC2 animals or plants cannot be housed outside of a PC facility.

Please refer to the Animal Welfare SWMSs 'mouse: transportation' and 'rat: transportation' for minimum welfare standards required for the transportation of animals. These SWMSs are available from the Animal Welfare website:

<http://www.flinders.edu.au/research/researcher-support/ebi/animal-ethics/resources/sops.cfm>

Packaging/containment:

- All packaging of GMOs for transport must occur within the PC facility that the GMO is currently housed in. GMOs must not be removed from transport containers outside of the destination PC facility.
- The type of containers used to provide necessary containment of GM microorganisms will vary depending on the type of organism and material transported.
 - Dry waste containing GMOs, but not containing any sharps, may be contained in two sealed plastic bags, supported inside a third, unsealed, rigid container that protects the bags from being torn or pierced during transport.
 - Small volumes of viable cultures may be transported within sealed, unbreakable tubes (primary), placed inside of an unbreakable box (secondary).
 - Large volumes of viable cultures may be transported within sealed Schott bottles (primary), placed inside of an unbreakable box (secondary).
 - When transporting plants that contain GM microorganisms that could form aerosols during transport, and where the plant requires ventilation during transport, consideration must be given to whether the vents of the primary or secondary containers should be HEPA-filtered.
 - Small animals (e.g. mice) containing GM microorganisms should be transported in sealed (clipped) cages with HEPA-filtered vents (Individually Ventilated Cages, IVCs).



Clipped IVC for transport of animals containing GM microorganisms, or GM animals containing Risk Group 2 microorganisms.

- When transporting PC2 animals within a building or between two certified facilities, the sealed cage should be placed inside of the locked PC2 trolley, available from the College of Medicine and Public Health Animal Facility (Animal Facility).



Lockable PC2 trolley available from the Animal Facility

- Following use for transport, the primary and secondary containers must either be decontaminated before reuse or disposal, or disposed of via the biohazard (yellow) waste stream.

Packaging with coolants:

- When transporting with coolants, it is preferable for the coolants to be used outside of the secondary container (e.g. tubes containing culture (primary container) placed inside of a sealed plastic box (secondary container) placed within an Esky containing water ice).
- Where the material to be transported is to be cooled using dry ice, liquid nitrogen or any other coolant that will release a gas, then a mechanism to allow the escape of the gas must be included.
- If water ice is used as a coolant then the outer packaging must be constructed so as to prevent any leakage.
- All containers must be able to withstand the temperature to which they are subjected.

Labelling:

- Before transport occurs, GM materials must be clearly labelled to indicate to other handlers that the item to be transported is, or contains, a GMO. The outermost container containing PC2 microorganisms must also have a biohazard label attached.
- Before transport occurs, the outermost container must be labelled to clearly show the name, address and contact details of the sender, so that the sender can be contacted should the container be lost, damaged or misdirected.
 - This is not required when the transport takes place entirely within one building, or when waste containing viable GMOs is being transported for the purposes of decontamination or disposal.



Outermost container showing clear labelling, biohazard symbol and contact details of sender

Accounting requirements:

- Procedures must be in place to ensure that all transported GMOs (or primary containers for cultures of GMOs) can be accounted for. This is to ensure that loss of GMOs during transport, or the failure of delivery, can be detected.
 - This can be achieved by counting and recording all GMOs or primary containers both before transport occurs, and again once the GMOs have reached the final transport destination.
 - When GMOs are being transported by a courier to an external recipient, the Flinders researcher should count and record the number of GMOs or primary containers before transport, and should contact the intended recipient (preferably via email) to confirm in writing that the same number of GMOs has been received.

Security arrangements:

- Access to GMOs must be restricted, by any means that is effective, to only persons approved by the IBC to handle the GMO.
 - This can be achieved by keeping containers in a locked area until collection, or by an approved person accompanying GMOs at all times during transport.

Decontamination:

- Prior to transport, the external surface of the primary and any required secondary container must be decontaminated using a suitable disinfectant (refer to Appendix F of *Australian/New Zealand Standard 2243.3:2010 Safety in Laboratories: Part 3: Microbiological Safety and Containment* for a list of suitable disinfectants).
- All containers used for transport of GMOs must be decontaminated after transport.
- Any materials transported with the GM microorganisms (e.g. soil, bedding materials, feed, etc.) must be either retained with the organisms under containment, or must be decontaminated after transport has occurred.
- Please refer to the Animal Welfare 'SWMS for mouse: PC1, PC2 and infectious containment husbandry' for special conditions relating to decontamination of waste, cages and carcasses of animals containing GM and pathogenic microorganisms. This SWMS is available from the Animal Welfare website:
<http://www.flinders.edu.au/research/researcher-support/ebi/animal-ethics/resources/sops.cfm>

Loss, spill or escape of GMOs during transport:

In the event of an escape, unintentional release, spill, leak, or loss of GMOs, including failure of GMOs to be delivered to an intended recipient:

- Within Flinders University, refer to the spill or unintentional release flowchart available within each PC facility on campus, and also from the Biosafety website:
<http://www.flinders.edu.au/research/researcher-support/ebi/biosafety/resources/forms.cfm>
- If safe to do so, contain and decontaminate spills and take steps to locate and retrieve GMOs and return GMOs to containment or render them non-viable.
- If an animal containing a GM microorganism escapes within a certified PC facility, trapping devices must be used to capture the animal and the animal must be returned to its container/cage or euthanized.
- Any real or suspected unintentional release of GMOs outside of a certified PC facility must be reported to the IBC Chairperson (Pam Sykes - ph. 0408722674) or IBC Executive Officer (Jess Hall - ph. 72218353) as soon as reasonably practicable.

NOTE: a person preparing a PC2 GMO for transport should consider whether the transported material should be accompanied by instructions on how to decontaminate the material in the event of a spill/leak, as well as any equipment or decontamination agent necessary to undertake the decontamination.

7. Contacts, Definitions and References

Contacts:

Position	Name	Contact details
IBC Executive Officer	Jess Hall	ibcadmin@flinders.edu.au ph. 72218353
IBC Chair	Prof Melissa Brown	melissa.brown@flinders.edu.au ph. 82012747
Manager, Animal Facility	Roxanne Collingwood	roxanne.collingwood@flinders.edu.au ph. 82044380

Definitions:

- **Physical containment (PC) facility:** There are four levels of physical containment applied to facilities certified by the Regulator (PC1–PC4). These are arranged in order of ascending stringency of containment requirements, which reflect the level of risk involved in the dealings that can be undertaken at each level. The required PC level for the containment of a dealing is governed by the *Act* and the *Regulations*.
- **Primary container:** A container immediately surrounding the GMO.
- **Sealed:** Able to contain all GMOs or the reproductive material of GM plants or GM aquatic organisms (including pollen or gametes) being transported or stored, and able to remain closed during all reasonably expected conditions of transport and storage.
- **Secondary container:** The container immediately surrounding the primary container.
- **Unbreakable:** Able to withstand all reasonably expected conditions of transport and storage such as: the forces, shocks and impacts expected during handling; or changes of temperature, humidity or air pressure.
- **Viable:**
 - **Microorganisms, cells and cell cultures** – able to survive or multiply even though resuscitation procedures may be required (e.g. when sub-lethally damaged by being frozen, dried, heated or affected by chemicals, including decontamination agents).
 - **Other organisms, whole or part** – able to live and grow independently of its parent or source organism, or able to reproduce or contribute genetic material to reproduction (e.g. sperm, ova, pollen, seeds, vegetative propagules).

References:

- *Guidelines for the Transport, Storage and Disposal of GMOs:*
<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/tsd-guidelines-toc>
- *Australian/New Zealand Standard 2243.3:2010 Safety in Laboratories: Part 3: Microbiological Safety and Containment:* <https://www.saiglobal.com/online/autologin.asp>
- *Flinders University Biosafety Manual* (March 2015):
http://www.flinders.edu.au/research/researcher-support/ebi/biosafety/biosafety_home.cfm

8. SOP Review

This SOP currently applies to transport of GMOs from dealings approved by the Flinders University Institutional Biosafety Committee. This SOP will be reviewed every 5 years, but will also be updated more frequently as policies, procedures and requirements change.