Flinders University

# Standard Operating Procedure
# Storage of Genetically Modified Organisms

| SOP Number: | SOP prepared by: | Date created: |
|---|---|---|
| IBC_SOP_5 | Jess Hall | January 2016 |
| **IBC approval date:** | **Contact:** | **Review date:** |
| 17/02/2016 | ibcadmin@flinders.edu.au | January 2021 |

## 1. Relevant Legislation and Policies

- *Gene Technology Act 2000*
- *Gene Technology Regulations 2011*
- *Guidelines for the Transport, Storage and Disposal of GMOs*
- *Commonwealth Quarantine Act 1908*
- *Flinders University Policy on Research Practice 2001*

## 2. Biosafety 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.

## 3. Safe Work Method Statement

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 store GMOs as part of your approved IBC project (see section 5 for restrictions on storage of GMOs).

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. Restrictions on Storage of GMOs

As outlined in the OGTR *Guidelines for the Transport, Storage and Disposal of GMOs*, the following restrictions apply to the storage of GMOs:

- Whole, viable** GM animals must not be stored outside of an authorised physical containment facility without permission, in writing, from the OGTR. This restriction does not apply to the sperm, fertilised eggs or embryos of GM animals.
- Whole, viable** GM plants must not be stored outside of an authorised physical containment facility without permission, in writing, from the OGTR. This restriction does not apply to the pollen, seeds, tubers, bulbs, corms or dormant stems of GM plants.
- GMOs must not be stored in a site that is prone to flooding, storm surges or other natural disasters.

** Please see the definitions given on page 4 for further description of viable organisms.

## 6. Requirements for the Storage of GMOs

**Packaging/containment:**

- All GMOs, including any non-GM organisms which contain GMOs, must be stored inside of a sealed, unbreakable primary container, packed inside of a sealed, unbreakable secondary container.
- The type of containers used for primary and secondary containment will vary depending on the type of organism being stored, but should always meet the requirements necessary to prevent the stored GMO from being released.
    - e.g. GM plant seeds may be stored inside of a sealed plastic bag (primary) inside of a plastic Tupperware container or sealed cardboard box (secondary).
    - e.g. small volumes of GM microorganisms may be stored inside of sealed vials or tubes (primary) inside of a Cryo/freezer box (secondary).
- In the case of a small storage unit such as a refrigerator, freezer or cryogenic storage container, the storage unit is permitted to be the secondary container.
- Following use for transport, the primary, and any secondary container that is not a storage unit (i.e. fridge, freezer), must be decontaminated prior to reuse or disposal.

**Storage location:**

- The IBC must be notified of the location of any stored GMOs held on campus, including any changes to the approved storage location (via email: ibcadmin@flinders.edu.au).
- Consideration should be given to whether the storage place is in a secure location (see security requirements below for further information).
- Consideration should also be given to the type of surfaces in the storage location. Ideally, surfaces should be smooth, impermeable to water, cleanable, and resistant to damage by decontamination agents that would be used to decontaminate any spill.
- GMOs must not be stored unless a supply of decontamination agents effective against the GMOs being stored is readily available in the storage location.

- All containers of decontamination agents must be labelled with the contents, and where necessary, the expiry date. Decontamination agents must not be used after their expiry date.

**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 GMOs in a storage unit (e.g. fridge, freezer, cryogenic storage container, cupboard) within a locked room, or by locking all storage units that are in a non-secure location.

**Labelling:**

- Stored GM materials must be clearly labelled to indicate to other handlers that the item is, or contains, a GMO.
- The primary container must be labelled to clearly show the name or other identifier of the GMO being stored.
- The storage unit (e.g. fridge, freezer), or any other secondary container, must be labelled to clearly show the name and contact details of the Chief Investigator responsible for the GMOs, so that the person can be contacted should any GMOs be spilled or lost.
- The storage unit or any other secondary container containing PC2 microorganisms must also have a biohazard label attached.

**Accounting requirements:**

- Procedures must be in place to ensure that all stored GMOs can be accounted for.
- Record(s) of stored GMOs must be maintained by the person storing the GMOs, and must be kept up-to-date at all times. The record must be made available to the IBC and/or OGTR upon request.
- The storage record(s) must be specific enough such that the person storing the GMOs is able to find the exact location of where the GMO is stored.
- The storage record(s) must indicate the corresponding IBC approval number related to the stored GMO.

**Unintentional Release:**

In the event of an unintentional release, spill, leak or loss of GMOs from storage:

- 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
- Efforts must be implemented as soon as reasonably practicable to locate and/or retrieve lost GMOs and return the GMOs to containment or render them non-viable.
- 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.

Consideration should also be given to whether the stored material should be accompanied by:

- instructions on how to decontaminate any material in the event of a spill or leak
- appropriate protective clothing for persons undertaking any decontamination; and
- any other equipment necessary to undertake decontamination.

## 7. Contacts, Definitions and References

**Contacts:**

| Position | Name | Contact details |
|---|---|---|
| IBC Executive Officer | Jess Hall | ibcadmin@flinders.edu.au<br>ph. 72218353 |
| IBC Chair | Prof Melissa Brown | melissa.brown@flinders.edu.au<br>ph. 8201 2747 |

**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/about_research_files/Documents/ebi/ibc/Flinders%20University%20Biosafety%20Manual.pdf

## 8. SOP Review

This SOP currently applies to the storage 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.