Biosafety - Labelling, Storage and Transport of Genetically Modified Material Procedure

Section 1 - Summary

(1) This Procedure outlines the labelling, storage and transport of genetically modified (GM) material.

Section 2 - TEQSA/ASQA/ESOS Alignment

(2) HESF: Standards 2.3 Wellbeing and Safety; 4.1 Research; 4.2 Research Training; 5.2 Academic and Research Integrity.

Section 3 - Scope

(3) This Procedure applies to:

a. all staff handling or supervising work with genetically modified organisms, or working in an Office for Gene Technology Regulator (OGTR) certified containment facility;
b. any external persons accessing University facilities and handling or supervising work with Genetically Modified Organisms (GMOs) or working in a University OGTR certified containment facility;
c. all GMOs that are in storage. This procedure does not apply to materials or animals being actively worked on (e.g. Live animals or plants, eukaryotic cell or bacterial cultures under experimental conditions prior to storage); and,
d. transport of GM material. If GM material is used, this procedure should be read in conjunction with the OGTR Guidelines for the Transport, Storage and Disposal of GMOs (2011). Transport of GM Material can be internal within the university or external to other organisations or locations.

(4) All work involving GMOs must be conducted in accordance with the Gene Technology Act 2000 and associated regulations. All persons working with GMOs should be aware of the relevant legislation, regulations and guidelines that apply to transport, storage and labelling of GMOs.

(5) It is a requirement of the Office of the Gene Technology Regulator (OGTR) that adequate storage records and labelling are in place to easily identify biological samples stored both inside and outside certified facilities. This enables both the separation and identification of different types of biological material stored and the easy identification of stored GMO samples during audits by the OGTR. In shared spaces and group storage areas, accurate labelling and record keeping is important.

(6) This Procedure provides detailed instructions and examples for storage and labelling of GM samples in fridges, freezers, cold rooms, liquid nitrogen dewers, etc., to meet the requirements of the Office of the Gene Technology Regulator (OGTR).

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Section 4 - Definitions

(7) Biological Material: Includes but is not limited to: blood, blood products, tissues, body fluids and any derivatives produced by chemical or physical means; micro-organisms – wild type or mutant; plants and plant material.

(8) Biosafety: Measures relating to the protection of an environment or population etc. from contamination with or infection by a biological agent

(9) Dealing: A dealing is any activity involving a GMO. Dealings are described as either an Exempt Dealing, a Notifiable Low Risk Dealing (NLRD), a Dealing Not Involving Release (DNIR) or a Dealing Involving Release (DIR). Dealings include:

a. conduct experiments with the GMO;
b. make, develop, produce or manufacture the GMO;
c. breed the GMO (includes housing of GMO);
d. propagate the GMO;
e. use the GMO in the course of manufacture of a thing that is not the GMO;
f. grow, raise or culture the GMO (includes storage of GMO);
g. import the GMO;
h. transport the GMO;
i. dispose of the GMO (includes decontamination process);

and includes to possess, supply, or use the GMO for the purposes of, or in the course of, a dealing mentioned in any of paragraphs (a) to (i).

(10) PC1, PC2, PC3 and PC4 certified facilities: Physical Containment facilities certified by the OGTR. PC1 is the lowest level of containment and PC4 is the highest level of containment. VU is only licenced for operations at levels PC1 and PC2.

Section 5 - Policy/Regulation

(11) Biosafety Policy

Section 6 - Procedures

Part A - Summary of Roles and Responsibilities

Roles	Responsibilities
Deputy Vice-Chancellor, Research & Impact(DVC-RI)	Responsible to the Vice-Chancellor for VU's Institutional Biosafety Committee (IBC) and its implementation of requirements as specified by regulatory bodies in relation to the handling of Biological Risk Group Agents.
Executive Director, Research Services	Responsible to the DVC-RI to ensure that the Manager, Research Infrastructure and Biosafety, advises and reports on the regulatory and legislative requirements on the handling of Biological Risk Group Agents, and is adequately supported to develop, implement, monitor, and review associated procedures and guidelines.
Senior Manager, Research Infrastructure & Biosafety	Authorised to advise on and report to the IBC on legislative requirements for the handling of Biological Risk Group Agents.

Roles	Responsibilities
Directors, Executive Deans and Heads of Department	Responsible for ensuring that all staff and students receive appropriate information and training necessary for them to handle Biological Risk Group Agents in accordance with all legislative requirements.
Manager, Technical Services	Responsible for ensuring that designated research spaces are adequately supported so that Biological Risk Group Agents can be handled in a compliant and safe manner. Ensure that Technical Managers have resources to develop and implement training and procedures necessary to ensure that all handling of Biological Risk Group Agents is in accordance with all legislative requirements.
Technical Managers	Ensure that all end-users of Biocontainment facilities are adequately trained and competent, and that there are procedures in place to ensure that all Biological Risk Group Agents are handled in accordance with regulatory and legislative requirements.
Project Supervisor / Subject Coordinator (including Principal/Chief Investigators, Academic Supervisors, Research Supervisors and Unit Conveners	Responsible for the health and safety of the undergraduate and postgraduate students they supervise, in addition to volunteers and staff employed under them. Ensure that students and staff are aware of and abide by VU's procedures for the handling of Biological Risk Group Agents.
Staff, Students, Volunteers and External Users of University Facilities	Ensure that they follow safety guidelines and abide by VU's Procedures for handling of Biological Risk Group Agents, as set out by VU and their respective Technical Manager and Project Supervisor/ Subject Coordinator. Ensure that their actions do not put themselves or any other individual at risk.
Senior Officer, Animal Ethics and Biosafety	Acts as the IBC Secretary and as such is responsible for receiving and sending communications between Project Supervisor/ Subject Coordinator, end-users, facility managers/supervisors and the IBC.

Part B - Categories of GMOs

(12) Dealings are classified based on the risk to the researcher, community and environment. The level of regulatory scrutiny is proportional to the level of risk. At VU, all classes of dealings must be reviewed by the IBC prior to commencement. The four categories of dealings are:

a. Exempt dealings – very low risk dealing requiring assessment by the IBC;
b. Notifiable Low Risk Dealings (NLRD) – requires assessment by the IBC and reported to the OGTR;
c. Dealings Not Involving Intentional Release (DNIR) – requires assessment by the OGTR;
d. Dealings Involving Intentional Release (DIR) – requires assessment by the OGTR.

(13) Detailed descriptions of each category are available on the Biosafety & Biocontainment SharePoint site.

(14) The Chief Investigator managing the project must first determine the correct classification of the proposed GMO dealing(s) by referring to the Gene Technology Regulations 2001 (Cth), Schedules 2 and 3. Information on the classifications of GMO dealings is also provided on the Biosafety & Biocontainment SharePoint site.

(15) NLRD's, DNIRs and DIRs are further classified into four categories according to the physical containment they require:

Category	Type and Containment	Condition
Exempt	Strongly Recommend meet PC1 standards	Good lab practice.
NLRD	PC1 PC2 PC3 (N/A)	OGTR storage and labelling requirements apply, as per the OGTR Guidelines and this procedure.

Category	Type and Containment	Condition
DNIR	PC2 PC3 (N/A) PC4 (N/A)	OGTR storage and labelling requirements apply, as per the OGTR Guidelines and this procedure. Any conditions as stipulated in the individual permit must be followed.
DIR	"Controlled release"	Any conditions as stipulated in the individual permit must be followed.

(16) OGTR Guidelines stipulate that storage and labelling requirements apply to GMOs categories in PC1-PC4.

(17) Any material covered by a DNIR regardless of the PC category, must be stored and labelled according to the conditions stipulated in the individual licence as issued by the OGTR. In some cases, projects may contain GM material from more than one category of dealing. It is important to distinguish between the different material and their storage, labelling and disposal requirements. Please see OGTR Guidelines for the Transport, Storage and Disposal of GMOs for more information.

Part C - Labelling Requirements for GM Material

Labelling of PC1 and PC2 GMOs for Storage

(18) Stored GM materials must be clearly labelled to indicate that the item is, or contains a GMO. The primary container must be clearly labelled to show the name or other identifier of the GMO being stored.

(19) The storage unit or any other secondary container, must be clearly labelled to show the name and contact details of the person responsible for the dealings, so that person can be contacted should any GMOs be spilled or lost.

(20) A biohazard label must be attached to any storage unit when storing any GM microorganism that satisfy the criteria for the classification of a Biological Risk Group 2 Agent as defined in AS/NZS 2243.3.

Labelling of PC1 and PC2 GMOs for Transport

(21) A person or accredited organisation supplying the GMO for transport must label the material to be transported in a manner capable of notifying any other handler of the material that the item to be transported is, or contains a GMO. Please refer to the Biosafety - Dealings Involving Genetically Modified Organisms Procedure for further information.

(22) When a service provider is undertaking the transport, then the outermost container must be clearly labelled to show the name, address and contact details of the sender, so the sender can be contacted should the container be lost, damaged or misdirected.

Part D - GM Material Storage Requirements

(23) Chief investigators must ensure that storage of GMOs complies with the requirements of the OGTR Guidelines for the Transport, Storage and Disposal of GMOs. Storage must be restricted to authorised GMOs, which is those covered by current assessment or licence.

(24) Technical Managers must maintain records of GMO storage in the facility. The location of GMO storage devices must be included in the GMO application if the storage is not within the certified facility.

(25) All GMOs must be labelled and stored in a safe and secure manner that prevents unauthorised access, mix-up or inadvertent release. GMOs may be stored either within or outside of certified facilities provided relevant OGTR Guidelines are adhered to. Specific requirements for the storage of GMOs are detailed in the OGTR Guidelines for Certification of Physical Containment Facilities, such as Level 2 Laboratory, Level 2 Animal Facility or Exempt Dealings.

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a. The IBC must approve of any storage of PC1 or PC2 GMOs outside of a certified facility and the approval must be noted in the NLRD record of Assessment.
b. Whole, viable GM plants or animals must not be stored outside of a certified facility without written permission from the Regulator. This restriction does not apply to pollen, seeds, tubers, bulbs, corms or dormant stems of GM plants.
c. GMOs must not be stored in a site that is prone to flooding, storm surges or other natural disasters.

(26) Many researchers at VU have GM work that falls into Exempt and NLRD categories and therefore may currently store the material in the same way. It is important to distinguish between exempt and other GM work.

a. If material is mixed, it must be treated at the higher requirement, e.g. if Exempt and PC2 NLRD GM material is stored together in the same freezer box, then all material must be treated as PC2 NLRD GM material.
b. GM and non-GM items must be segregated, or records kept to show this; or all items must be treated as GM including labelling the secondary container and storage unit with "Contains GM items/GMO".
c. Furthermore, if any non-GM items that have not been segregated are to be moved or transported, they must be treated the same as GM items from that facility (e.g. if moved from a PC2 facility, they must be treated as PC2 material and only moved to or used in other PC2 certified facilities).

Storage of PC1 and PC2 GMOs, including organisms that contain GMOs

(27) Storage and labelling of GMOs must be in accordance with the current OGTR Guidelines for the Transport, Storage and Disposal of GMOs. All GMOs must be clearly labelled to identify the GMO.

(28) All GMOs, including any non-GM organisms which contain GMOs, must be stored inside a sealed primary, unbreakable container, packed inside of a sealed, unbreakable secondary container.

a. E.g. microtube or a sealed locked bag of GM materials (primary container) must be stored within a sealed plastic container (secondary container).
b. E.g. sealed plastic container (primary container) inside a refrigerator, freezer or other cryogenic storage unit (secondary container).

(29) 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.

(30) Following use for transport, the primary and secondary container that is not a storage unit (e.g. fridge, freezer) must be decontaminated prior to reuse or disposal.

(31) Storage locations must be listed on the relevant NLRD.

(32) An approved, active NLRD is required to store any PC2 GMOs that are classified as NLRD category.

Storage of GMOs assessed as DNIR or DIR

(33) Any material covered by a DNIR or DIR licence must be stored as per the licence conditions and according to its PC category. e.g. PC2 material should be double contained.

(34) If the licence storage conditions are different to the OGTR Guidelines for the Transport, Storage and Disposal of GMOs, then the licence conditions must be followed.

Security Arrangements for Storage of GMOs

(35) Access to GMO storage must be restricted to only persons approved by the IBC to handle the GMO. This can be

achieved by:

a. Keeping the 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;
b. Granting access only to those mentioned on the IBC project, who have completed the appropriate training and have the experience to deal with GMOs.

Part E - Transport of GMOs

(36) Please refer to the Biosafety - Importing and Exporting Biological Material Procedure, Biosafety - Packaging and Transport of Biological Materials Procedure and Biosafety - Dealings Involving Genetically Modified Organisms Procedure. In brief:

a. All GMOs must be transported in accordance with the OGTR Guidelines for the Transport, Storage and Disposal of GMOs and may include specific licence conditions. This requires that the GMOs are packaged and handled in a manner that ensures their containment throughout the transport process.
b. Transport may also require the inclusion of the Infectious substances Dangerous Goods 6.2 symbol, the relevant UN number and compliance with AS 4834, IATA Dangerous Goods Regulations and United Nations Dangerous Goods requirements.
c. A documented accounting process must be implemented to ensure that all GMOs that have been sent are received at the correct delivery point.

(37) As defined in the OGTR Guidelines for the Transport, Storage and Disposal of GMOs, transport includes movement of GMOs:

a. from one certified physical containment (PC) facility to another;
b. between a certified PC2 facility and a storage location outside of an authorised facility;
c. between a place of storage to another place of storage;
d. between any points specified in a licence to an authorised PC facility;
e. or waste containing GMOs from a certified PC facility, or from storage outside a certified PC facility;
f. to a place where the GMOs are to be decontaminated or disposed of (e.g. to an autoclave or incinerator from an authorised PC facility;
g. imported into Australia from the Australian border to a certified PC facility or a storage location outside of an authorised PC facility; or to a place where GMOS are to be decontaminated or disposed of;
h. to be exported from Australia from the time the GMOs leave a certified PC facility or a storage location outside of an authorised PC facility until the GMOs have left Australia.

Transport of GM Material from VU Campuses

(38) A person or accredited organisation supplying the GMO for transport must label the material to be transported in a manner capable of notifying any other handler of the material that the item to be transport is, or contains a GMO.

(39) The outermost transport container must be labelled clearly to 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.

(40) PC1 and PC2 GMOs may 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 or destruction. Live PC1 and PC2 animals or plants cannot be housed outside of a PC facility.

(41) When transporting GMOs to another facility or location outside of the certified facility, the GMOs must be

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transported with the following:

a. A labelled primary sealed container, which is contained within a secondary sealed, unbreakable container.
b. A label stating ‘GMO’ affixed in a prominent position on the outermost container.

(42) All packaging of GMOs for transport must occur within the PC facility the GMO is currently housed in. GMOs must not be removed from the transport containers outside of the destination PC facility.

(43) A person consigning the GMO for transport should consider whether the transported material should be accompanied by:

a. Instructions on how to decontaminate the material in the event of a spill or leak;
b. Sufficient volume of effective decontamination agent to decontaminate any spill;
c. Appropriate protective clothing for persons undertaking the decontamination;
d. Any other equipment necessary to undertake decontamination.

(44) Procedures must be in place to ensure that all GMOs (or for microorganisms and cell cultures, the number of primary containers of GMOs transported) can be accounted for and that a loss of GMOs during transport, or the failure of delivery can be detected.

a. E.g. both sender and recipient keep records of the transport and verify the records for consistency;
b. This is not required when transport takes place entirely within a building provided the GMOs are accompanied by an IBC authorised person:

(45) Primary and secondary containers must be decontaminated or destroyed after transport.

(46) If needing to transport GM Material, liaise with either the facility Technical Manager or Animal Ethics & Biosafety Officer to determine who is the appropriate authorised person on campus to provide assistance.

Transport of GM Material within VU Buildings and Campuses

(47) GM material may be transported by person, providing the GMO falls into the GMO exempt or PC1 NLRD or PC2 NLRD category, and is NOT a Risk Group 2 infectious microorganism (as defined in AS/NZ 2243.3).

a. The GMO must have primary and secondary containment (e.g. microfuge tubes within a sturdy ziplock bag);
b. The primary container must be clearly labelled as containing GMOs;
c. Ice blocks or gel packs may be used as a coolant, provided they are placed outside the secondary containment (e.g. outside of the ziplock bag but within a hard esky);
d. The outermost container (e.g. hard esky or carry bag) must be clearly labelled with the sender contact details (e.g. a luggage tag may be used) including 24 hour contact in case the bag is lost or stolen). The label must also have a biohazard marking;
e. The container must be accompanied at all times by an IBC authorised person;
f. A list of the items being transported should be kept with the transport container and should be accessible without opening the inner package (e.g. may be placed in an envelope in the carry bag, or may be placed in a clear invoice type envelope attached to the esky);
g. Record of transport including list of all items transported, must be kept and verified by the sender and recipient laboratories;
h. The recipient laboratory must be IBC certified to an appropriate level (e.g. PC1 or PC2).

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Transport of GM Animals

(48) GM Animals must be wholly contained inside a sealed, unbreakable container.

(49) Secondary containment is not required for small animals containing GM microorganisms (e.g. mice) if being transported in a sealed cage filled with HEPA-filtered vents. For further information, refer to the AEC SOP for Transport of GM Animals.

Actions following loss, spill or escape of GM material during transport

(50) In the event of escape, unintentional release, spill, leak or loss of GMOs, including failure of the GMOs to be delivered to the recipient.

(51) Every effort must be made to locate and retrieve the GMOs and return them to the container, or render them non-viable (e.g. using a chemical disinfectant).

(52) The Senior Manager, Research Infrastructure & Biosafety and the Regulator must be notified of any adverse events that occurred during transport as soon as reasonably practicable. Refer to the Biosafety - Non-Compliance and Adverse Incidents Procedure.

(53) Procedures must be in place to ensure that all GMOs (or for micro-organisms and cell cultures, the number of primary containers of GMOs transported) can be accounted for and that a loss of GMOs during transport, or the failure of delivery can be detected (i.e. both sender and recipient keep records of the transport and verify the records for consistency).

(54) This is not required when transport takes place entirely within a building provided the GMOs are accompanied by an IBC authorised person.

Part F - Transport of GM Waste

(55) Waste being transported for decontamination inside the same building and which has no substantive amount of liquid containing GMOs, and will not give rise to aerosols containing GMO’s during transport must be contained in two unbreakable containers, at least one of which must be sealed.

Decontamination of containers

(56) The outermost container must be free of contamination prior to transport, and the outer surface of the primary containers must be free of contamination prior to transport.

(57) Unless kept in a certified facility, decontamination of all containers (including wheelie bins, trolleys and eskies) is required after transport.

Infectious GMOs

(58) If the GMO is a Risk Group 2 agent, a biohazard label is also required on the outermost packaging and should be treated as per Category A or Category B material as outlined in the Biosafety - Packaging and Transport of Biological Materials Procedure.

(59) These materials should only be transported between campuses using an approved courier (or approved waste contractor in the case of GM waste transport).

(60) This is not required where transport takes place entirely within a building, providing it is conducted by an IBC authorised person.

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Part G - Record Keeping Requirements and Security

(61) A record of GMOs stored must:

a. be kept and made available to the Regulator upon request,
b. allow the person storing the GMOs to find the exact location of where the GMOs are being stored.

(62) During the storage of GMOs outside of an authorised physical containment facility, access to the GMOs must be restricted by any means that is effective, to only a person or class of persons mentioned in an IBC's record of assessment as having the appropriate training and experience to deal with the GMOs.

Part H - Contingency Planning

(63) Contingency plans for fridge, freezer or cold room failure should be considered, and include ensuring any GMO samples are transported and stored following OGTR Guidelines for the Transport, Storage and Disposal of GMOs. Storage records should be updated to reflect the current location of GMOs, as should any GMO dealings.

Part I - Other Considerations

(64) When closing down a project, all GMOs must either be destroyed or transferred and maintained under an approved, active dealing. Evidence of destruction should be filed and notice sent to the IBC.

(65) If GMOs are spilled while in storage or transit to storage, decontamination of the primary containment and associated melted ice/ice etc. is required prior to any maintenance.

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