Biosafety - Dealings Involving Genetically Modified Organisms Procedure

Section 1 - Purpose / Objectives

(1) The purpose of this procedure is to protect the health and safety of people, animals and the environment, by identifying risks posed by, or as a result of, dealings with Genetically Modified Organisms (GMOs) at VU.

(2) At all times, dealings with GMOs must be conducted in accordance with the Gene Technology Act and associated regulations. Dealings must also comply with the University's health and safety systems including the Risk Management Program and Biosafety Program. These programs ensure compliance with other State and National Acts and Regulations, as well as Codes of Practice, and Australian Standards.

(3) A copy of the regulations and standards can be found on the Biosafety Website .

Section 2 - Scope / Application

(4) This procedure applies across the University to all personnel handling or supervising work with Genetically Modified Organisms, or working in an Office for Gene Technology Regulator (OGTR) certified containment laboratory.

(5) All personnel must ensure their work is compliant with the relevant regulations, codes and standards at all times.

Section 3 - Definitions

IBC	Institutional Biosafety Committee - is a Governance committee of the Unviersity, established in accordance with written guidelines issued by the OGTR under the Gene Technology Act.
Office of the Gene Technology Regulator (OGTR)	The OGTR was established by the federal government to support the Gene Technology Regulator administer the national regulatory system for gene technology as set out in the Gene Technology Act (the Act). The Act and Gene Technology Regulations (the Regulations), in conjunction with corresponding State and Territory legislation, underpin the national scheme for the regulation of live and viable GMOs in Australia (including GM microorganisms)GM animals and GM plants).
OHS	Occupational Health and Safety
Licensee	The person named on the Victoria University licenses and accreditation applications as the license holder.
Competent Person	A person who has acquired through training, qualification or experience the knowledge and skills to carry out the task.

Dealing	In relation to a GMO, a dealing is described as either Exempt, 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).
Genetically Modified Organism (GMO)	a. an organism that has been modified by gene technology; b. an organism that has inherited particular traits from an organism (the initial organism), being traits that occurred in the initial organism because of gene technology; c. anything declared by the Regulations to be a genetically modified organism, or that belongs to a class of things declared by the Regulations to be genetically modified organisms; but does not include: d. a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy; e. an organism declared by the Regulations not to be a genetically modified organism, or that belongs to a class of organisms declared by the Regulations not to be genetically modified organisms. The Regulations provide specific definitions for genetically modified guinea pigs, mice, rabbits and rats.
Gene Technology	Any technique for the modification of genes or other genetic material. It does not include: a. sexual reproduction; b. homologous recombination; c. any other technique specified in the Regulations for the purposes of this paragraph. NB: Gene Editing Technologies (e.g. Crispr/Cas9 system), although not technically classified as gene technologies by the OGTR, are reviewed by VU's IBC via the high risk project application process.

Section 4 - Policy Statement

(6) See Biosafety Policy.

Section 5 - Procedures

Accreditation

(7) The Vice-Chancellor is the University's Licensee and as such has ultimate responsibility for the maintenance of the University's status as an accredited organisation under the gene technology legislation.

(8) The Vice-Chancellor has delegated the task of managing compliance in laboratories and high risk project approval to the Provost & PVC (Research & Research Training).

(9) The Director, Office for Research is responsible for the development, compliance monitoring and review of this procedure and any associated guidelines.

(10) The Manager, Research Infrastructure and Biosafety, Research Services, is responsible for the implementation of

this procedure.

(11) The IBC, and the person listed as the contact between the OGTR and the University (Director of Research & Manager, Research Infrastructure and Biosafety), provide assistance in meeting the compliance requirements.

(12) The University must comply with all conditions described in the OGTR Guidelines for the Accreditation of Organisations.

Institutional Biosafety Committee (IBC)

(13) The University must establish an IBC. The membership and collective technical expertise of the IBC must meet the University's needs and must include an independent member.

(14) The Committee must be supported, resourced and appropriately indemnified. The operation of IBC must be in accordance with its documented VU IBC Terms of Reference .

Reporting to the Office of the Gene Technology Regulator (OGTR)

(15) As an Accredited Organisation, the University must submit an Annual Report to the Gene Technology Regulator.

Gene Technology training and competency

(16) The University's training program structure is detailed in the Dealings Involving Risk Group Agents Procedure .

(17) The University will provide gene technology information, and training regarding OGTR behavioural requirements, for staff and postgraduate students (including Honours students) and for personnel from Affiliated Organisations.

(18) Technical Services Managers must ensure that Technical Staff are competent before they are placed in charge of an OGTR certified containment facility.

(19) Technical Staff must ensure that access to a facility is confined to persons who are trained in a specific set of behaviours appropriate to the facility itself and to the dealings being conducted in that facility. The Colleges (and Technicians maintaining the laboratories for them) must ensure that all persons working in the certified facility are instructed in any specific OGTR-imposed conditions of certification and any variations on that certification.

(20) The IBC may request evidence of the competency at any time.

(21) Academic & Professional Staff supervising End-users, or listed as listed as Chief Investigators must:

a. ensure that their staff and students are inducted into the facility, including any specific behavioural requirement appropriate to the facility;
b. inform their staff and students of the specific licence conditions, and any specific facility-certification conditions;
c. ensure that all staff and students who are working with the DNIR have signed a training and information statement related to the specific information contained in the DNIR licence;
d. ensure that all work is covered by a documented procedure;
e. ensure that their staff and students are competent before they undertake any GMO dealing;
f. retain IBC assessment records for 8 years from the date of assessment;
g. retain evidence of training;
h. provide ongoing information and appropriate supervision;
i. provide appropriate training and supervision for undergraduate and short term students.

OGTR Certified Physical Containment Facilities

Determine facility certification requirements

(22) Exempt dealings are not required to be carried out in an OGTR certified facility. All other GMO dealings require that the facility is certified with the OGTR.

(23) The level of containment (PC1- 4) for GMO dealings will be determined by the risk group of the dealing.

Oversight of facilities

(24) The University must ensure that all facilities in which GMO dealings are conducted have a designated Laboratory Technician.

(25) The Colleges must ensure that the type of OGTR certification for the facility remains appropriate to the risk associated with the GMOs with in the facility.

Facility Safety Manual/Standard Operating Procedures

(26) Laboratory Technicians and Animal Facility Technicians must ensure that the facility has current, documented procedures in place, preferably in the form of a safety manual.

(27) The safety manual should include:

a. all general and specific conditions of certification relevant to the physical containment level and type, as detailed in the relevant OGTR Guidelines for Certification of Physical Containment Facilities.
b. The specific work practices for the facility.
c. Documented risk assessments, the identified controls.
d. Laboratory maintenance requirements and records.
e. Standard operating procedures.
f. Training and supervision requirements for personnel.

OGTR-certification of facilities

(28) Based on an assessment of current and proposed GMO dealings, Laboratory Technicians and Animal Facility Technicians must determine whether a facility is required to be certified by the OGTR, and to which containment level.

(29) The level of containment (OGTR PC1-4) for GMO dealings will be determined by the risk group of the dealing, as described in OGTR Guidelines.

(30) If certification is required, the Laboratory owner must apply to the IBC by using the Application for Certification of a Facility Form and arrange with the Manager, Research Infrastructure and Biosafety for the facility to be inspected, and to document that the facility meets the required conditions for certification.

(31) The completed application form and a detailed floor plan must be submitted to the IBC who will review it and arrange for it to be signed by the Vice-Chancellor. The completed documentation is then sent to the OGTR by the Manager, Research Infrastructure and Biosafety.

(32) Approval by the OGTR can take 90 working days from the date of receipt of the application. Until written approval is received, there must be no dealings involving GMOs in that facility.

Inspection of OGTR-certified facilities

(33) Physical containment facilities must be inspected prior to OGTR-certification. Inspection will be arranged by the

IBC by an IBC authorised inspector.

(34) All OGTR-certified facilities must be inspected annually. The IBC will arrange this and provide an inspection report to the Laboratory Technicians and Animal Facility Technicians. The report must be made available to University or to the OGTR on request.

(35) Independent of the annual inspection, the Manager, Research Infrastructure and Biosafety and IBC may randomly inspect a laboratory at any time.

(36) The legislation allows the OGTR to undertake scheduled, or spot inspections of all certified facilities.

Corrective action following inspection

(37) Corrective actions must be completed before the OGTR will issue a certificate.

(38) Where an inspection report identifies any non-compliance with the OGTR conditions of certification, the Laboratory Technicians and Animal Facility Technicians must provide written confirmation to the IBC with within a reasonable timeframe, that corrective actions have been completed. Failure to comply may result in a delay in receiving the certification from the OGTR, or the suspension (or cancellation) of certification by the OGTR.

Working in an OGTR-certified facility

(39) Where GMO dealings are required to be conducted in a certified facility, Laboratory Technicians and Animal Facility Technicians must ensure that these dealings are not undertaken until the certification documents are received from the OGTR and the necessary signage is displayed.

(40) All OGTR requirements for a certified facility must be complied with at all times by all personnel. This includes when non-GMO work is being performed in the facility.

Variation of to a Facility OGTR certification

(41) Changes to the type of agents used, work conducted or space utilised in a certified facility may necessitate changes to the requirements that a facility must meet in order to afford the appropriate level of containment and ensure the safety of personnel working in those facilities. A risk assessment must be performed by the work group and submitted to the IBC for consideration.

(42) All requests to vary a certificate must be signed off by the University before being presented to the OGTR.

(43) Any proposal to vary, suspend or surrender a current OGTR facility certification must be submitted by the Facility Manager to the IBC via the Manager, Research Infrastructure and Biosafety. The Manager will liaise with the OGTR on behalf of the IBC. The variation must not be implemented without the written approval from the OGTR.

(44) The OGTR will issue new certification stickers which must be affixed in place of the previous stickers. Where a facility has had the certification surrendered or suspended, all OGTR certification stickers must be removed from the doors.

Decommissioning/Surrendering physical containment facilities

(45) After a laboratory group has vacated or a project ceased in an OGTR-certified physical containment facility, or their portion of one, the Academic or Professional Staff member in charge of the project or group, must ensure that the area is free from hazards, GMOs, and has been fully decontaminated.

(46) Areas, equipment and surfaces that need to be disinfected must be identified (including bench tops, floors, surfaces of equipment, glassware and other potentially contaminated places such as hoods, water baths, centrifuges, refrigerators, incubators, walls, sinks etc.). The appropriate disinfectant needs to be identified (see AS/NZS 2243.3

Appendix F) and used according to this Standard and the manufacturer's recommendations.

(47) Where the entire facility has been vacated, all door signage must be removed from access doors if the signage is no longer relevant to the hazards contained in the facility. In particular, the certification door stickers issued by the OGTR must be removed once the certificate has been surrendered.

(48) The Manager, Research Infrastructure and Biosafety may suspend or lift suspension of as a result of non-compliance or to allow maintenance or renovations to be performed. Work with hazardous infectious agents or potentially hazardous biological material is not permitted in a facility for which the certification has been suspended.

(49) All documentation must be retained with the College for 8 years.

Assessment and conduct of GMO dealings

(50) Dealings are classified based on the level of 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 three main classes of dealings are: Exempt Dealings, Notifiable Low Risk Dealings (NLRD) and Licensed Dealings.

(51) Detailed descriptions of each class and corresponding application forms are available on the Biosafety website .

Determining the classification of GMO Dealings

(52) Chief investigator managing the project must first determine the correct classification of their proposed GMO dealing(s) by referring to the Gene Technology Regulations 2001, Schedules 2 and 3. Information on the classification of GMO dealings is also provided on the Biosafety website .

Project application involving GMOs

(53) All GMO dealings must be assessed by an IBC.

(54) No GMO dealing is to commence until the Chief investigator managing the project receives written notice from the IBC stating that the dealing can begin.

(55) The IBC requires that the GMO applications are signed by the person responsible for the facility.

(56) The names, qualifications, experience and training level of all key research staff must be included.

(57) The University requires that all GMO applications and variations to GMO applications by researchers to be approved by the IBC.

(58) Chief investigator managing the project must use the relevant OGTR project application form when applying to the IBC for an assessment of projects involving Exempt dealings and/or NLRDs. Application forms should be downloaded from the Biosafety website to ensure the latest version of the form.

(59) Applications must be in word and directed in electronic format to the IBC secretary from the project Chief Investigator. The signatures page can be scanned and sent as a separate pdf file.

(60) Where a researcher has a grant application approved through the University, but has their GMO work assessed by an IBC other than the University's IBC, the University's IBC must be notified of the nature of the project.

(61) For any dealing involving a DNIR, the OGTR DNIR application form on the OGTR Website must be used. DNIR applications must only include information about the DNIR. Any GMOs that are classified as Exempt or NLRD and that are part of the research must be assessed separately by using the GMO application form forwarded to the IBC secretary.

(62) Professional staff managing the project must not commence or allow anyone else to commence, any GMO dealing without obtaining the written assessment of the project from the IBC for Exempt dealings and NLRDs, or receiving the DNIR licence from the OGTR.

Obtain assessment for GMO dealings

(63) Completed GMO application forms should be submitted to the IBC secretary. The combined application form for Exempt dealings and NLRDs needs to be downloaded from the HS web pages to ensure the latest version of the form. Application forms for DNIRs are to be downloaded from the OGTR website.

(64) Applications for Exempt dealings will be forwarded to an individual IBC member who has expertise in the relevant area. Once assessed, the information will be forwarded to the PVC (Research and Research Training). Chief investigator managing the project should receive the Notice of the IBC assessment in a few weeks from receipt, depending on whether further information is required.

(65) Applications for NLRDs and DNIRs must be assessed by the full IBC, as described in the Gene Technology Regulations 2001. Applications must be received by the IBC no later than two weeks prior to a scheduled committee meeting. The IBC meets quarterly, usually the first Thursday of the third month of each quarter. Information is on the Gene Technology web page.

(66) NLRD applications will be assessed at the IBC meeting and the information will be forwarded to the PVC (Research and Research Training). The Chief investigator should receive the Notice of the IBC assessment within a few weeks of the meeting, depending on whether further information is required.

(67) DNIR application forms must be submitted to the IBC secretary at least two weeks before a scheduled meeting, for assessment by the IBC and monitoring by the PVC (Research and Research Training). Applications are then forwarded to the OGTR for the issuance of a licence. It will take up to 90 working days after the date of receipt for the OGTR to issue the licence, and may take longer if further information is required.

Conduct of GMO Dealings

(68) The Chief investigator must ensure that their GMO dealings are conducted in accordance with the IBC-assessed conditions, the OGTR Guidelines, and any OGTR-imposed licence conditions. Procedures must comply with the Facility Safety Manual, for the facility in which the dealings are conducted.

(69) The Chief investigator must manage all occupational health and safety risks of their project in accordance with the University's Risk Management Program, the Biosafety Procedure and AS/NZS 2243.3 .

(70) Records of IBC assessment must be kept for 8 years from the date of assessment. NLRDs must be reassessed every 5 years as a new application as required by the OGTR regulations. Exempt dealings approval is indefinite or until such time the regulations change.

Annual/Final Project reports

(71) Chief Investigators must submit an Annual Progress Report to the IBC as a condition of project approval. Chief Investigators who fail to submit an annual progress report may have their approval revoked.

(72) Chief Investigators must submit a Final Report within three months of the expiry date or conclusion of their project as a condition of project approval. Final reports are reviewed by the IBC and kept by the University as an official record for 8 years.

(73) Annual Progress Report Forms and Final Report Forms are available on the Biosafety Website .

Amendments and Variation of project assessment or GMO licence

(74) The University requires that all GMO applications and variations to GMO applications by researchers are signed off by the IBC.

(75) The IBC must be notified in writing ASAP of any changes to an Exempt dealing or NLRD project, as it was described in the original application for assessment by the IBC. This might include such things as changes to key personnel, the addition of a similar GMO, altered facility conditions or storage locations. Any changes to projects are to be signed off by the IBC.

(76) Any variation, transfer or suspension of a DNIR licence must be made in writing to the Regulator by the Manager, Research Infrastructure and Biosafety, and following approval by the IBC. The proposed change must not be implemented until written approval is received, which may take up to 90 days from the date of receipt. Please contact the Manager, Research Infrastructure and Biosafety in the first instance to assist you with this and to help ensure that the correct channels are followed.

Transport and supply of GMOs

(77) Please see the Import, Export, Transport and Packaging of Biological Material 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 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 DG 6.2 symbol and the relevant UN number, and compliance with AS 4834, IATA & UN 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.
d. Before requesting any GMO to be supplied, the Professional Staff managing the project must ensure that the correct certifications, assessments, controls and licences are in place (including import permits). The source of the supply should be included on the GMO Application form.
e. If you have a licence for a DNIR, you must not supply that DNIR to another party unless it is a condition of the licence. Variations can be requested if there is a need to supply when it is not a condition of the current licence.
f. Chief investigators in both the receiving and requesting facility or organisation must ensure that the correct approvals (i.e. NLRD, Licence) are in place to hold, use, transport and supply GMOs.
g. Chief investigators must maintain records relating to GMO supply, receipt, storage and disposal. See Biological Risk Group Agent Sample Inventory Table.

Storage and disposal of GMOs

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

(79) Unauthorised GMOs or GMOs not covered by a current IBC assessment must be destroyed.

(80) All GMOs must be labelled and stored in a safe and secure manner that prevents unauthorised access, mix-up, or inadvertent release. Specific requirements for storage of GMOs are detailed in the OGTR Guidelines for Certification of Physical Containment Facilities.

(81) Facility 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.

(82) GMOs from Exempt dealings and NLRD must disposed of in accordance with the OGTR Guidelines for the transport, storage and disposal of GMOs. DNIR disposal must meet the requirements of the licence.

Maintain Gene Technology Records

(83) Gene technology records must be maintained and be made available for inspection and audit. The following gene technology records must be maintained.

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(84) Minutes of meetings, correspondence, applications considered and findings, facility inspections and corrective action, register of certified facilities, register of approved projects, gene technology hazards/incidents and recommendations/actions, internal and external reporting.

College

(85) Gene technology risks and risk controls must be incorporated into the local OHS Hazard and Risk Register.

Laboratory Technical Staff & Animal Facilities Staff

(86) Facility certification and any approved variation, register of GMO dealings conducted in the facility, register of authorised personnel and evidence of training/competency, register of authorised GMOs stored in the facility.

(87) Validation and calibration of autoclave(s), biosafety cabinets, waste disposal and chemicals used to decontaminate GMOs.

Chief investigators directly responsible for the care of End-users & End-users

(88) Project assessments and any variation, supply and receipt of GMOs, register of stored GMOs for projects.

Non-compliance & Adverse incidents

(89) Please see Non-Compliance and Adverse Incidents Procedure. In brief:

a. Non-compliances may relate to the structural or physical attributes of an internally certified facility, to the work practices and / or the behaviour of personnel. The University, via the IBC, must notify the OGTR if it identifies any non-compliance with the conditions of accreditation, laboratory certification or project approval. Failure to rectify non-compliances by the clearance dates may result in the certification of the facility being suspended or revoked. The IBC and/or Manager, Research Infrastructure and Biosafety may recommend to the Director of Research to suspend or revoke a certification, or close a facility, if: repeated or serious non-compliances are observed, or non-compliances are not remedied by the clearance date.
b. All adverse incidents (and near misses) must be reported via the OHS portal. OHS must provide the IBC with a report of all incidents involving biologicals or occurring in containment laboratories.
c. All biohazardous adverse incidents (and near misses) or non-compliant (or suspected non-compliant) incidents involving GMOs must be immediately reported to the IBC by calling the IBC Emergency Phone (0481 001 329). Types of incidents include: non-contained spills of GMOs or potentially hazardous biological material, all laboratory acquired infections, breach of containment and escape of transgenic animals.
d. The IBC will formally investigate and seek a written explanation of the incident from the Chief Investigator (or other relevant persons) on the incident using the IBC Incident Form.

Review

Monitor Compliance

(90) The Manager, Research Infrastructure and Biosafety monitors compliance with this procedure.

(91) The IBC must provide an annual report on biosafety to the Director of Research for reporting to the relevant committee of Council.

(92) The University is subject to monitoring and audit by the OGTR and must submit an Annual Report to the Gene Technology Regulator.

Section 6 - Guidelines

(93) Nil

Section 7 - Supporting documents

(94) A copy of the legislation can be downloaded from the: VU Governance & Secretariat Website.

(95) All supporting documents can be found on the Biosafety Website or by contacting the Manager, Research Infrastructure and Biosafety (ibc@vu.edu.au).

(96) The following Procedures have been referenced in this document:

a. IBC P004 Import, Export, Transport & Packaging of Biological Material Procedure
b. IBC P005 Non-Compliance and Adverse Incidents Procedure
c. IBC P006 Biosafety Governance Procedure

(97) The following Forms have been referenced in this document:

a. IBC F005 Biohazard Material Project Application Form
b. IBC F006 Incident Report Form
c. IBC F007 OGTR Notification of Exempt Dealing Form
d. IBC F008 Application for a NLRD PC1 & PC2 Form

(98) The following Documents have been referenced in this procedure

a. IBC D004 Biological Risk Group Agent Sample Inventory Table
b. IBC D013 Terms of Reference

Status and Details

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Effective Date	14th September 2016
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