USING BIOLOGICALS AND ANIMALS PROCEDURE

SCOPE

This procedure relates to all activities involving the use of biologicals and/or animals under the management and control of Monash University in Australia and applies to affected workers, students, contractors and visitors.

PROCEDURE STATEMENT

This procedure sets out the requirements for the purchase, handling and disposal of biologicals and/or animals in accordance with the relevant legislative requirements and standards.

1. Abbreviations

AA	Approved Arrangement
BPD	Buildings and Property Division
DAWE	Department of Agriculture, Water and the Environment
DNA	Deoxyribonucleic Acid
EPA	Environment Protection Authority
GM	Genetically Modified
GMO	Genetically Modified Organism
GT	Gene Technology
IBC	Institutional Biosafety Committee
LAA	Laboratory Animal Allergy
MTLD	Monash Talent and Leadership Development
OGTR	Office of the Gene Technology Regulator
OHS	Occupational Health and Safety
OH&S	Monash Occupational Health & Safety team, led by the Health, Safety and Wellbeing Manager
OREI	Office of Research Ethics and Integrity
PC	Physical Containment
SDS	Safety Data Sheet
SWI	Safe Work Instructions

2. Risk Management

2.1 OHS Risk Management must be completed in accordance with the OHS Risk Management Procedure**:**

2.1.1 Before activities using biologicals and/or animals can commence;

2.1.2 Before procuring new biologicals and/or animals or related equipment;

2.1.3 Before the introduction of new procedures, processes or equipment that use biologicals and/or animals; and

2.1.4 When procedures or processes or equipment that use biologicals and/or animals are modified.

Further guidance on what to include in the risk assessment can be found in the Risk Management Guidelines: Biologicals

2.2 Safe Work Practices

2.2.1 Following the completion of risk assessments, Safe Work Instructions (SWIs) must be developed and should include training requirements, appropriate personal protective equipment, Immunisation and/or Health Surveillance requirements and First Aid and Emergency procedures.

2.2.2 Further guidance and a template are provided in the Guidelines for the Development of Safe Work Instructions.

3. Procurement

3.1 Prior to procuring biologicals, you must check with the Office of Research Ethics and Integrity (OREI) regarding:

3.1.1 Requirements for licenses, permits or notification to use the biologicals; and

3.1.2 The physical containment (PC) requirements or Approved Arrangement (AA; previously known as Quarantine Approved Premises, QAPs) classification for use and storage of the biological.

3.2 Prior to procuring biologicals, you must check with your Biosafety Officer regarding:

3.2.1 The availability of appropriate handling conditions for the biological, e.g. biological safety cabinets;

3.2.2 The availability of appropriate emergency facilities and procedures required for the biological; and

3.2.3 The appropriate waste disposal procedures required for the biological.

3.3 SDS

When purchasing biologicals, verify that the SDS for the biological is available in ChemWatch. If the SDS is not available, it must be requested from the supplier, manufacturer or importer.

A copy of all SDSs not currently held in the ChemWatch database must be forwarded to ChemWatch to be included.

4. Importation of Biologicals

4.1 Biosecurity (Quarantine) Requirements

All biological material brought into Australia directly by Monash workers and students is subject to biosecurity requirements as set out in the Biosecurity Act (2015) and Biosecurity Regulations (2016). General information regarding the importation of biologicals can be obtained from the Department of Agriculture, Water and the Environment (DAWE) website by following the links to the Biosecurity Import Conditions System (BICON), or from the OREI Biosecurity website.

4.2 Permits

Before importing ANY biologicals from overseas, Monash workers and students must obtain the appropriate importation documents through the OREI. Workers should not apply for permits directly via the DAWE.

4.3 Facilities

In certain circumstances, the DAWE may require work with specific imported biologicals be conducted within an Approved Arrangement (AA) site/facility. Such facilities must be of a physical containment level specified by the DAWE and must be inspected by the OREI and certified by the DAWE prior to the importation of biologicals.

5. Facilities & Safe Work Practices for Work with Biologicals

5.1 Types of Facilities

5.1.1 Facilities for the use of biologicals are defined by the Gene Technology Act, Biosecurity Act and Australian standards for Laboratory design and construction (AS/NZS 2982) and Safety in the laboratory (AS/NZS 2243.3).

5.1.2 Facilities certified by the Office of the Gene Technology Regulator (OGTR) for research involving recombinant DNA technology are signed with OGTR signs denoting the containment level and facility type. Facilities certified by the Department of Agriculture, Water and the Environment (DAWE) for research with specified imported biological materials are signed with yellow Approved Arrangement (AA) signs. PC1 – PC4 facilities as defined by AS/NZS 2243.3 will only have a Biological Hazard sign.

5.2 Containment Levels under the AS/NZS 2243.3

AS/NZS 2243.3 defines levels of Physical Containment (PC) for working with biologicals. At Monash University we have facilities that are classified into three such physical containment levels; PC1, PC2 and PC3. PC1 is the minimal level and describes most general laboratory areas including most teaching laboratories; whereas PC3 is the highest level of containment at Monash University and is required for work involving infectious pathogens.

5.3 PC1 Laboratory Facilities

5.3.1 Emergency drench showers and eyewash stations must be available at a distance of no more than 15 metres or within approximately 10 seconds travel time from any position in the laboratory. Where these facilities are not available, alternate arrangements should be made in consultation with the OHS Consultant/Advisor for the area.

5.3.2 Bench tops must be able to withstand heat generated by general laboratory procedures.

5.3.3 Chairs/stools must be ergonomically suitable for the tasks and adjustable to work with the heights of benches and other equipment. The material must be smooth and impervious to water to facilitate cleaning.

5.3.4 Wash basins with hot and cold water, or an alternative means of decontaminating hands, must be provided inside each laboratory near the exit.

5.3.5 Open spaces between and under benches, cabinets and equipment must be accessible for cleaning.

5.3.6 Write up areas must be separated from work/study areas to minimise the chance of reading and writing materials being contaminated or damaged.

5.4 Personal Protective Clothing and Equipment

5.4.1 Laboratory workers must wear protective clothing when performing procedures in the laboratory. The use of long-sleeved cotton or polyester wrap around gowns or laboratory coats is recommended.

5.4.2 Protective eyewear must be worn by workers when working in the laboratory, unless lesser requirements can be justified by risk assessment. On the other hand, some procedures may require full face protection as determined in the risk assessment for the procedure.

5.4.3 Closed footwear must be worn by workers when working in the laboratory.

5.4.4 The above three items are the minimum personal protective equipment requirements for a laboratory unless lesser requirements can be justified by a risk assessment. Contact your OHS Consultant/Advisor for assistance in assessing such risk.

5.5 Work Practices

5.5.1 Eating, drinking, shaving and the application of cosmetics is prohibited in laboratories.

5.5.2 Food and drink for consumption must not be stored in laboratories or laboratory refrigerators or freezers.

5.5.3 Long hair must be tied back.

5.5.4 All hazardous work must be identified, assessed for their risk and controls implemented where necessary.

5.6 PC2 Laboratory

The conditions for PC2 laboratories listed below are in addition to those for PC1 laboratories.

5.7 Facilities

5.7.1 The ceilings, walls and floors must be smooth, easy to clean and impermeable to liquids, and resistant to commonly used reagents and disinfectants.

5.7.2 Hand wash basins must be fitted with hands-free operation type mixers or suitable alternatives discussed with your OHS Consultant/Advisor.

5.7.3 A pressure steam sterilizer must be available where steam sterilizing of infectious waste is required onsite.

5.7.4 Suitable coat hooks must be provided near the entry/exit of the laboratory and lab coats must be laundered regularly.

5.7.5 A supply of clearly labelled disinfectants for decontamination purpose must be available.

5.7.6 All equipment must be decontaminated prior to maintenance, service or removal.

5.7.7 Liquid effluents must be discharged in a manner appropriate to the type of waste and as determined by the Risk assessment and in compliance with trade waste agreements.

5.7.8 Laboratory ventilation must be set up to ensure a graduated negative pressure with the directional airflow moving inwards to the laboratory working area. The air handling must be set up by specialist air handling engineers.

5.8 Containment Equipment

5.8.1 Biological safety cabinets must be used when working with specimens containing microorganisms transmissible by the respiratory route or when work produces a significant risk from aerosol production.

5.8.2 Centrifuges that are used for human samples or infectious microorganisms must be fitted with either a sealed rotor or aerosol-tight, sealed safety buckets. Samples should also be placed in sealable tubes.

5.9 Personal Protective Equipment

Suitable gloves must be worn when handling human blood, body fluids or tissue, or microorganisms or when working in biological safety cabinets.

5.10 Work Practices

5.10.1 Access to PC2 laboratories must be restricted to appropriately trained workers and students.

5.10.2 Workers and students must receive instruction and training appropriate to the specimens handled.

5.10.3 Workers and students must attend Biosafety training (see Section 13).

5.10.4 Particular care should be taken when handling and disposing of any sharps to avoid accidental self- inoculation.

5.10.5 All clinical samples must be treated as infectious.

5.10.6 All visitors to the laboratory including Buildings and Property Division (BPD) workers must be inducted appropriately and must be made aware of any specific hazards in the area.

5.10.7 No one must enter the laboratory for cleaning, servicing of equipment, repairs or other maintenance activities before relevant potentially contaminated laboratory surfaces have been disinfected and authorisation has been obtained from the Safety or Biosafety Officer.

5.10.8 Any procedure, which may produce aerosols of potentially infectious material, must be performed in a biological safety cabinet.

5.10.9 A container of viable microorganisms must be transported between facilities or to steam sterilizers in a sealed secondary unbreakable container, which can be readily decontaminated prior to transport.

5.10.10 All potentially contaminated equipment must be either steam sterilized or chemically disinfected after use.

5.10.11 Separate report writing and long-term write up areas must be provided outside the laboratory.

5.11 PC3 Laboratory

The conditions for PC3 laboratories listed below are in addition to those for PC1 and PC2 laboratories.

5.12 Facilities

5.12.1 The laboratory must be separated from all other areas and must not be accessible by the general public.

5.12.2 Entry to the laboratory must only be through a double door airlock system. Doors must be self-closing, open outwards with the outer door being lockable. Both doors must be fitted with seals to limit air leakage. Doors must contain glass viewing panels so that observation of the laboratory occupants may be possible.

5.12.3 All equipment must be decontaminated prior to maintenance, service or removal.

5.12.4 An emergency two-way communication system, or an alarm system, must be provided in addition to the telephone.

5.12.5 A pressure steam sterilizer for decontamination of laboratory wastes must be available and located within the laboratory.

5.12.6 Liquid effluents must be discharged in a manner appropriate to the type of waste and as determined by the Risk assessment and in compliance with trade waste agreements.

5.12.7 Laboratory ventilation must be set up to ensure a graduated negative pressure with the directional airflow moving inwards to the laboratory working area. The air handling must be set up by specialist air handling engineers.

5.13 Containment Equipment

5.13.1 Where a central reticulated vacuum system or portable pumps are used, a 0.2 µm hydrophobic membrane-type filter, and liquid disinfectant trap must be installed at the point of use.

5.13.2 Where required, a class III biological safety cabinet must be made available.

5.14 Work Practices

5.14.1 Workers and students must be trained in handling the specific pathogens used in the laboratory.

5.14.2 Laboratory door/s must be locked when unoccupied.

5.14.3 All work with risk group 3 organisms must be conducted in a biological safety cabinet.

5.14.4 No one must enter the laboratory for cleaning, servicing of equipment, repairs or other maintenance activities before relevant potentially contaminated laboratory surfaces have been disinfected and authorisation has been obtained from the Safety or Biosafety Officer.

5.14.5 Protective clothing must not be worn outside of the laboratory and must be sterilised before laundering.

5.14.6 Outer clothing and personal effects must not be taken into the laboratory.

5.14.7 An emergency evacuation plan must be devised and made available to all workers and students working in the facility, OH&S and Monash Security.

6. Human Clinical Samples

6.1 Human clinical samples are to be treated as potentially infectious unless categorically known to be otherwise. For that reason, all clinical samples are to be used in facilities that meet PC2 facility and procedural requirements as described in Section 5. However, if organisms from a higher risk group are isolated or suspected to be found in a clinical sample then the sample should be treated as per that risk group and used in a higher containment facility.

6.2 Procedures that will create significant aerosols must be performed in biological safety cabinets.

7. Microorganisms

7.1 Risk Groups

Microorganisms are divided into risk groups 1 (lowest risk) – 4 (highest risk) based on their risk to health and safety.

7.1.1 A list of risk group 2, 3 and 4 organisms can be found in AS2243.3, section 3.3 (Tables 3.1-3.11).

7.1.2 The risk group classification has been established to match the physical containment level of the facility where the work is to be conducted, e.g. risk group 2 organisms must be handled in a PC2 facility.

7.2 Facilities

Facilities where work with microorganisms is to be performed must meet the building requirements and procedural requirements for the physical containment level corresponding to the appropriate physical containment level of that microorganism.

8. Animals

The use of animals at Monash University must comply with all relevant Victorian and federal government legislation.

Applications for approval to use animals for scientific purposes must be made through the ERM online system.

For all ethical matters relating to the use of animals for research, contact the Monash Animal Ethics Office.

8.1 Facilities

Facilities for the housing and care of laboratory animals are defined in the Victorian Code of Practice for Housing and Care of Laboratory Mice, Rats, Guinea Pigs and Rabbits and the Australian Code for the Care and Use of Animals for Scientific Purposes (8th Edition, 2013) and must meet the minimum standards as set out in the Prevention of Cruelty to Animals Act. All further queries should be referred to the Monash Animal Ethics Office.

8.1.1 Animals can be held in a variety of containment facilities that are designed to ensure that the animals, and the microorganisms that may be being used in conjunction with the animals, do not escape from containment.

8.1.2 Whilst the general design is similar to that of laboratories, one key consideration is that of primary containment to prevent cross-contamination and exposure of personnel to allergens and microorganisms. Further details are outlined in AS/NZ 2243.3, section 6.

8.2 Transgenic or Knockout Animals

The use of transgenic or knock out animals must also meet the requirements of the OGTR as must the facilities where they are housed. General information regarding the use of GM animals can be obtained from the OGTR website or by contacting the OREI. Approval to use GM animals must be obtained from both the Institutional Biosafety Committee (IBC) and the Animal Ethics Committee before work can commence.

8.3 Occupational Health

It is important to be aware of the potential hazards and health risks associated with working with laboratory animals and to be aware of the precautions needed to prevent or adequately control exposure. The Occupational Health team can be contacted for advice on any aspects of the health issues associated with working with animals.

8.4 Laboratory Animal Allergy (LAA)

LAA is an allergic hypersensitivity response, which may develop as a result of exposure to animal allergens. The proteins most commonly associated with allergic reactions are found in animal urine, saliva and dander.

8.4.1 Anyone who has regular contact with laboratory animals and/or associated materials, e.g. animal litter has the potential to develop allergies to the animals they are working with.

8.4.2 Early symptoms of LAA may include nasal congestion and sneezing, dry and sore throat, watering and itchy eyes, rashes and itchy skin, as well as cough with asthma-like symptoms.

8.4.3 Continued exposure, may increase the severity of symptoms and infrequently sensitisation may occur. This can pose a significant health risk and early contact with the Occupational Health team is required.

Although those workers who have a personal history of allergy to common environmental allergens (atopy) and exposure to animals are at increased risk, individuals with no prior history of allergies and only brief work exposures can also develop LAA. Most workers will do so within three years of working with animals.

The best approach for reducing the likelihood of developing an allergic reaction is to eliminate or minimise exposure to the proteins found in animal urine, saliva, and dander. A comprehensive risk assessment and implementation of appropriate control measures should be undertaken prior to working with animals.

The following table will assist in assessing personal risk and determining the necessary control measures.

Risk level	Task	Controls
Low	Working with post mortem or with tissues Work on unconscious animals Procedures involving few animals Automated cage cleaning	Wear appropriate personal protective equipment (lab coat, gloves, respiratory protection)[1] Adhere to safe work instructions Assessment by Occupational Physician (case by case)
Medium	Cleaning within animal unit Indirect contact in animal room Feeding Animals	Wear appropriate personal protective equipment (lab coat, gloves, respiratory protection)[1] Assessment by Occupational Physician (case by case) Participate in Health Surveillance program, e.g. lung function test Adhere to safe work instructions Reduce airborne allergens when cleaning cages, i.e. wet cleaning Use low dust bedding materials
High	Injections and other invasive procedures Shaving Fur Handling animals Box changing Disposal of soiled litter Changing filters of local exhaust ventilation or room ventilation Washing cages.	Wear appropriate personal protective equipment (lab coat, gloves, respiratory protection)[1] Assessment by Occupational Physician (case by case) Participate in Health Surveillance program, e.g. lung function test Adhere to safe work instructions Reduce airborne allergens when cleaning cages, i.e. wet cleaning Use low dust bedding materials Ensure adequate ventilation, e.g. local exhaust ventilation or work within a Class II Biosafety cabinet for specific procedures Reduce the frequency and time spent with animals in high density rooms

[1] Although engineering controls can be useful in reducing exposure to animal allergens, airborne levels generated on direct contact to animals and bedding materials can still be significant. Respiratory protection of various types may be necessary to reduce exposure and must be fitted correctly. Advice on suitable and effective respiratory protection should be sought from OH&S.

8.5 Zoonosis

All workers and students working with animals may be exposed to microorganisms carried by the animals, which may also be able to infect humans under the right conditions. These microorganisms will be categorised into one of the risk groups as outlined in Section 7.1.

8.5.1 The passage of the microorganisms may occur via scratches, bites, urine, faeces or through aerosols generated by further manipulation of tissue harvested from animals.

8.5.2 Information on zoonotic disease associated with animals commonly used at Monash University is found in Appendix I.

8.5.3 The appropriate animal husbandry skills in conjunction with using appropriate personal protective equipment will reduce the risk of cross infection. In addition, adopting standard PC2 precautions and restricting processes likely to create aerosols to biosafety cabinets will also reduce the risk of zoonotic infection.

Further information and advice on zoonoses can be obtained from the Occupational Health team.

8.6 Infectious Animal Models

The considerations outlined in Section 8.3 also apply to research that involves the use of infectious animal models, where animals have been injected with infectious pathogens. Appropriate risk control measures must be in place prior to commencement and the Occupational Health team can be contacted for advice.

9. Health Surveillance

Those workers and students working with animals or other biological agents may be subject to health surveillance, which consists of the systematic monitoring of those "at risk" for any adverse effects of work on their health as it relates to their duties. This is delivered through medical assessment and biological monitoring (e.g. lung function testing). Workers working with animals may be subject to a pre-placement assessment to determine individual risk factors and baseline measurements.

Further details are outlined in the Health Surveillance Procedure.

10. Immunisation

As part of their work or study, Monash University workers and students may be at risk of exposure to infectious diseases including those that are vaccine preventable. Where the risk assessment demonstrates a need, workers and students must be offered the relevant vaccines in accordance with the Immunisation Procedure. The Immunisation grid should be used to determine immunisation requirements. For further assistance contact the Occupational Health team.

11. Pregnancy and Breastfeeding

Workers who are either pregnant, considering pregnancy or breast-feeding, should refer to the Protecting Unborn and Breast-Fed Children Procedure and seek out further information provided on the OH&S website or by contacting their OHS Consultant/Advisor, the Occupational Health Physician or Occupational Health Nurse Consultant.

12. Genetically Modified Organisms (GMOs)

12.1 Work/Study with GMOs

12.1.1 All work/study utilising recombinant DNA technology is controlled through the Office of the Gene Technology Regulator (OGTR). All Monash matters concerning Gene Technology are handled by the OREI.

12.1.2 General information regarding the use of GMOs and appropriate approval can be obtained from the OGTR website, or from the OREI Biosafety website.

12.1.3 Applications for approval to conduct Dealings with GMOs must be made through the ERM online system.

12.1.4 No work with GMOs can commence until the appropriate approval has been granted and the facility where the work is to be conducted has been certified by the OGTR.

12.2 Facilities

12.2.1 Facilities to be used for GMO work must comply with the requirements set out by the OGTR.

- Facilities must be of the appropriate physical containment level matching the type of GMO dealing being conducted.
- PC1, PC2 and PC3 facilities must meet the OGTR's guidelines for such facilities and be certified.
- The certification of facilities is managed by the OREI.

12.2.2 PC2 and PC3 facilities must be inspected annually by a person deemed competent by the Institutional Biosafety Committee (IBC) and PC3 facilities are also inspected routinely by the OGTR.

13. Training

The training needs of workers and students should be determined using the OHS training requirements matrix and meet the requirements of the OHS Induction and Training Procedure.

13.1 Biological Safety

Training in the use of biologicals must be provided at a range of levels, including local and at University level.

13.2 Local Training

13.2.1 Supervisors must ensure that induction and training in the use of biologicals is provided to workers and students under their supervision. This may be provided by local safety personnel or experts with specific knowledge of the biologicals used in the area and must include:

13.2.2 Identification of biological hazards in the area and the nature of the hazard including exposure routes;

13.2.3 The location of risk assessments and safe work instructions for the biologicals held and used in the area;

13.2.4 The use and location of personal protective and emergency equipment for the use with biologicals;

13.2.5 Local procedures, processes or equipment that use biologicals especially those resulting in the generation of aerosols;

13.2.6 Immunisation requirements for working with biologicals; and

13.2.7 Local biological waste handling, storage and disposal procedures.

13.3 University Level Training

13.3.1 Monash Talent and Leadership Development (MTLD) coordinates the Biosafety Basic Principles and Biosafety 2 training courses, which cover biological safety and working with GMOs and biosecurity-controlled goods. This training is mandatory for workers, Postgraduate and Honours students across all Australian campuses of Monash University.

13.3.2 Information regarding the content and scheduling of training courses offered is provided:

- At the MTLD website; and
- In the OHS training requirements matrix.

13.4 Animal Care and Use

All Monash University workers and students involved in the care and use of animals must complete the following two online training modules before they are eligible to be listed as an investigator on a Monash University Animal Ethics project:

- Animal Ethics 101 - Understanding your legal responsibilities (pre requisite for Animal Ethics 102)
- Animal Ethics 102 - Getting started - Using animals at Monash University

Information about the courses is available at the Monash Animal Ethics Office website.

The following practical training courses in Animal Handling are run for Monash workers and students by the Monash Animal Research Platform (MARP):

- Mouse or Rat - Administration of Substances and Blood Collection
- Rodent Anaesthesia
- Surgical Techniques in Rodents

Course information and dates are available from the MARP website

Training in other species is available on request by contacting the MARP Training Manager.

13.5 Training Records

In order for academic/administrative units and supervisors to demonstrate effectively that they have provided local training for the workers and students that they supervise; local training records must be kept and this should:

- Include training in specific procedures; and
- Be maintained in a folder in each area where training is provided.

The student or workers being trained must be able to demonstrate competence in the task/s before a record is completed.

OH&S has developed a proforma to use to record attendance at OHS training in each academic/administrative unit.

A short description of the points covered in the training should also be documented for all local biological training provided in the academic/administrative unit. The description will act as both a reminder regarding the areas that should be covered in the training and as a record of the areas covered in the training.

14. Waste Disposal

Correct biological waste management involves a structured program to ensure that any wastes generated are correctly identified in terms of their potential hazard to the environment and to any workers or students handling them.

14.1 All Biological Waste Must Be:

14.1.1 Handled by appropriately trained workers who are provided with appropriate personal protective equipment;

14.1.2 Segregated according to the particular hazards, treatment methods and recycling or re-use opportunities associated with the waste type, as outlined in the:

- Waste Disposal Summary table;
- Guidance on GMO Decontamination and Disposal; and
- Procedures for recycling waste from OGTR-certified facilities.

Note: The OREI must be contacted before implementing laboratory recycling programs for OGTR certified facilities. Recycling from AA sites is not permitted under any circumstances.

14.1.3 Further information on the disposal of sharps can be found in the document Syringes, Needles and Syringe Barrels – use & disposal.

14.1.4 Packaged to ensure that:

- The waste materials cannot escape the container at any time;
- Containers used conform to the colour coding and marking system specified by Australian standards, are fit for transport; and
- Will not pose risks to personnel handling the wastes such as infrastructure support workers and waste disposal contractors.

14.1.5 Clearly labelled identifying:

- The type of waste material;
- The major contaminant or risk associated with the waste;
- The academic/administrative unit who generated the waste and their contact details, e.g. phone number; and
- Date of generation;

14.1.6 OGTR-certified PC2 facilities:

- Waste must be disposed of at the point of use into bins that are lined with two yellow “Biohazard” bin liners in accordance with the Guidelines for the Transport, Storage and Disposal of GMOs version 1.1 (2011) for double-containing waste.

Note: Waste must be double-bagged before it is placed in the large biohazard waste collection bins provided by the waste contractor.

- Where Clinismart C64 and G64 bins are used, they can be used with a liner or without one. The bin liner must be tied off by a laboratory member and the lid locked securely into position prior to collection by the waste contractor.

Note: Sharps waste cannot be placed into these bins and should be disposed of into separate sharps bins.

- All GMO waste must either be disposed of as GMO waste (incinerated) or decontaminated prior to disposal as non-GMO, clinical waste.

14.1.7 AA sites:

- All Biosecurity waste must be disposed of only into bins labelled ‘Biosecurity waste’.

Note: There are strict holding times for Biosecurity waste before it must be collected for destruction.

14.1.8 Bins must be stored in a secure site/area specifically designated for the waste type and for the academic/administrative unit generating the waste, and refrigerated, if required. The waste store must comply with EPA bunding guidelines to ensure spills will not cause pollution or pose an environmental hazard.

14.1.9 Waste can be disposed of by a licensed EPA-prescribed waste contractor, however, where appropriate, waste may be autoclaved and disposed of to landfill in accordance with the Guidelines for the Transport, Storage and Disposal of GMOs version 1.1(2011), Sections 3.1.6 - 3.1.9, AS/NZS 2243.3:2010, Section 10.6 and/or import permit conditions and AA class requirements.

14.1.10 Waste must be transported in such a manner to ensure that the health of workers, students, visitors to the university, and/or the environment is not compromised and in accordance with Victorian EPA requirements and the Australian Dangerous Goods Code for the Transport of Dangerous Goods by Road and Rail.

14.1.11 For biological waste contaminated with radiation, the University's Radiation Protection Officer must be contacted.

14.1.12 In any other instance where the waste type is unclear, OH&S should be contacted for advice.

15. Emergencies Involving Biologicals and Animals

15.1 Incident and Emergency Response

15.1.1 Emergency procedures for a biohazard spill are contained in the Monash '333' emergency procedures booklet or on the Emergency Procedure posters (currently being rolled out) next to the Building Evacuation diagrams. For off-campus locations, local emergency procedures must be followed.

15.1.2 All incidents must be reported in SARAH and notified to your supervisor, Biosafety Officer and Safety Officer as appropriate.

15.1.3 Incidents involving GMOs (including unintentional release into the environment) must also be immediately reported to the Research Compliance Officer who will in turn notify the Institutional Biosafety Committee (IBC).

15.1.4 Incidents involving unintentional release of imported biological material that is under biosecurity control (e.g. spill outside an AA, incorrect disposal must be immediately reported to the Research Compliance Officer, who will in turn, notify the DAWE.

15.2 Crisis Management

15.2.1 Monash University has invested considerable resources on planning crisis management and recovery. This planning includes consideration regarding crises involving biologicals.

15.2.2 Further details and the crisis management plan are detailed in the Crisis Management Policy and procedures.

16. Responsibility for Implementation

A comprehensive list of OHS responsibilities is provided in the document OHS Roles, Responsibilities and Committees Procedure. A summary of responsibilities with respect to this procedure is provided below.

16.1 Monash Occupational Health & Safety (OH&S): The responsibilities of OH&S include:

16.1.1 Developing, maintaining, reviewing and auditing the University's policies, procedures and systems related to biological safety management;

16.1.2 Advising on appropriate immunisation; and

16.1.3 Providing information, instruction and training on biological safety management.

16.2 Office of Research Ethics and Integrity (OREI): The responsibilities of the OREI include:

16.2.1 Administering all matters relating to the Gene Technology Act 2000 (including the Gene Technology Regulations 2001) and Biosecurity Act 2015 and their discharge; and

16.2.2 Providing information, instruction and training on work involving GMOs or biologicals subject to biosecurity requirements.

16.3 Monash Animal Ethics Office: The responsibilities of the Monash Animal Ethics Office include:

16.3.1 Administering all ethical matters relating to the use of animals for research purposes; and

16.3.2 Providing information and instruction on regulatory issues, animal care and the Animal Ethics approval process.

16.4 Heads of Academic/Administrative Units: It is the responsibility of the Head of academic/administrative unit to ensure that procedures and systems are in place in their area to manage biologicals and/or animals effectively to ensure:

16.4.1 A healthy and safe environment for workers, students, visitors and contractors;

16.4.2 That local standards and practices comply with legislative requirements and university policy; and

16.4.3 That workers and students undertake recommended training in the use of biologicals and/or animals.

16.5 **Supervisors:** It is the responsibility of supervisors to ensure that procedures and systems are in place in the areas of their responsibility to manage biological and/or animals effectively to ensure:

16.5.1 A healthy and safe environment for workers, students, visitors and contractors;

16.5.2 That local standards and practices comply with legislative requirements and university policy; and

16.5.3 That workers and students undertake recommended training in the use of biological and/or animals.

16.6 **Biosafety Officers:** It is the responsibility of the Biosafety Officer to:

16.6.1 Advise, inform and instruct workers and students on the local use, storage, transport and disposal of biological substances, including appropriate equipment, facilities and work practices to prevent exposure to any harmful biological material and ensure appropriate containment;

16.6.2 Assist in local induction of new workers and students with regards to biosafety, OGTR and biosecurity matters;

16.6.3 Monitor the need and advise workers and students of availability and procedures for immunisation against potential biohazards;

16.6.4 Serve as a local source of expertise to the academic/administrative unit regarding biosafety, OGTR and biosecurity requirements including licensing, certification of facilities and classification of activities under the relevant legislation and standards;

16.6.5 Monitor local area compliance with biosafety, OGTR and biosecurity requirements with regard to the use and disposal of hazardous biological materials and recombinant DNA molecules;

16.6.6 Liaise with the University's Research Compliance Officer, OH&S, local OHS committee, head of academic/administrative unit and local Health and Safety Representative (HSR) in matters relating to biosafety, OGTR and biosecurity;

16.6.7 Review biosafety aspects of research projects and teaching activities and provide advice/assistance on document preparation, e.g. risk assessments, OGTR applications;

16.6.8 Develop and implement emergency response procedures for incidents involving biohazardous agents and materials;

16.6.9 Participate in workplace inspections of research and teaching facilities for compliance with regulations and guidelines pertaining to the use, handling, and disposal of potential biohazards and recombinant DNA;

16.6.10 Respond to and investigate all biosafety incidents occurring within the department, and develop corrective action plans; and

16.6.11 Report any breach of compliance to the Research Compliance Officer, who will in turn notify the Institutional Biosafety Committee (IBC) and OH&S.

16.7 **Workers and students**: Workers and students using biological and/or animals must comply with this procedure and any other relevant OHS instructions, policies and procedures using control measures and/or personal protective equipment to ensure their own health and safety as well as the health and safety of others.

17. Records

For OHS Records document retention please refer to: OHS Records Management Procedure

18. APPENDIX I - Examples of Zoonotic Diseases

Host[1]	Disease in Humans	Causative agent	Mode of transmission
Sheep	Brucellosis	*Brucella* spp	Direct contact with infected semen Foetuses, foetal membranes, Vaginal secretions
Sheep	Q-fever	*Coxiella burnetii*	Inhalation Direct contact with amniotic fluid or placenta
Sheep Non-human primates	Campylobacteriosis	*Campylobacter* spp	Ingestion (faecal-oral route)
Sheep Non-human primates	Tuberculosis	*Mycobacterium* spp	Inhalation Direct contact Ingestion (faecal-oral route)
Macaques	B virus encephalitis	*Macacine alphaherpesvirus* 1	Direct contact Bite wounds
Rodents Farm and wild animals	Leptospirosis Weil's disease (severe form of Leptospirosis)	*Leptospira* spp	Direct contact Urine Contaminated soil and water
Rodents Rabbits Sheep Farm animals	Ringworm	Fungal spp (*Trichophyton, Microsporum,, Epidermophyton)*	Direct contact Soil may be a reservoir
Farm animals Rodents Amphibians	Salmonellosis	*Salmonella* spp	Ingestion (faecal-oral route) Inhalation Direct contact
Farm animals Rodents Amphibians	Giardiasis	*Giardia duodenalis*	Ingestion (faecal-oral route) Direct contact
Birds	Psittacosis	*Chlamydia psittaci*	Inhalation Direct contact
Zebrafish Amphibians Aquarium water	Cryptosporidiosis Bacterial infections	Cryptosporidium (Protozoan) Various bacterial species	Direct contact Ingestion (faecal-oral route)
Bats	ABLV infection (Paralysis, Convulsions)	Australian Bat Lyssavirus	Bites/scratches

[1]The host examples listed in this table are those relevant to Monash University activities.

DEFINITIONS

Key word	Definition
Animals:	An animal is defined as any multicellular heterotrophic eukaryote belonging to the Kingdom Animalia (vertebrates and invertebrates). Under the Prevention of Cruelty to Animals Act the following require Animal Ethics approval: ● Any live non-human vertebrate (fish, amphibians, reptiles, birds and mammals) encompassing domestic animals, purpose-bred animals, livestock, wildlife, as well as cephalopod invertebrates such as octopus, squid, cuttlefish and nautilus. ● Any live prenatal or pre-hatched embryos, foeti and larval forms e.g. a mammalian or reptilian foetus, pre-hatched avian, mammalian or reptilian young and live marsupial young developed beyond half the gestation or incubation period of the relevant species, or they become capable of independent feeding. ● This is not required for insects, millipedes, annelids (worms), gastropods (slugs and snails) or spiders, shellfish (bivalves, mussels, oyster and scallop); eggs, spat or spawn of fish.
Biologicals	For the purpose of this document, the definition of a biological will include, but not be limited to blood, blood products, tissue, body fluids (e.g. urine, faeces, semen, vaginal secretions, pericardial fluid, cerebrospinal fluid, synovial fluid, pleural fluid, amniotic fluid, saliva, mucus, any fluid with visible blood) and any derivatives produced by chemical or physical means (e.g. protein, enzyme or blood fractions). In addition, it is intended to cover microorganisms (bacteria, viruses, parasites, fungi, prions) wildtype or mutant and plants and plant material. It is not intended to include live animals in this definition.
Biological Wastes	These are covered by Environment Protection Authority (EPA) Regulations and are legally known as “clinical and related” or prescribed wastes and include: ● Discarded sharps; ● Laboratory and associated wastes directly involved in specimen processing; ● Human and animal tissue, including materials or solutions containing or contaminated with blood or body fluids; ● Cytotoxic wastes; and ● Pharmaceutical wastes.
Gene Technology	For the purpose of this document gene technology is defined as any technique for the modification of genes or other genetic material, but does not include sexual reproduction, homologous recombination or any other techniques specified in Part 2, Division 2 of the Gene Technology Act (2000).
Genetically Modified Organism	For the purpose of this document a genetically modified organism (GMO) is defined as: ● An organism that has been modified by gene technology; ● An organism that has inherited traits from an organism (the initial organism), being traits that occurred in the initial organism because of gene technology; or ● Anything declared by the Gene Technology 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: ● A human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy; or ● An organism declared by the Regulations not to be a genetically modified organism, or that belongs to a class of organism declared by the Regulations not to be genetically modified organisms.
Organism	For the purpose of this document an organism is defined as a biological entity that in at least some form is capable of response to stimuli, reproduction or transfer of genetic material, growth and development, and maintenance of homeostasis.

GOVERNANCE

Parent policy	OHS&W Policy
Supporting schedules	N/A
Associated procedures	**Australian and International Standards** • ISO 45001:2018 Occupational Health and Safety Management Systems • AS/NZS 2982:1997 Laboratory design and construction • AS/NZS 2243.3:2010 Safety in laboratories Part 3: Microbiological aspects and containment facilities • AS/NZS 3816:1998 Management of clinical and related wastes • AS/NZS 4031:1992 Non-reusable containers for the collection of sharp medical items used in health care areas • AS/NZS 1319:1994 Safety signs for the occupational environment **Other Documents** • Guidance notes for the transport of Class 6.2 (infectious substances) dangerous goods (1997) • Guidelines for the Transport, Storage and Disposal of GMOs, Version 1.1 (2011) • Industry Code of Practice for the Management of Biohazardous Waste (including Clinical & Related wastes), 7th edition (2014) **Monash University OHS Documents** • Development of Safe Work Instructions Guidelines • Health Surveillance Procedure • Immunisation procedure • Management of Suspected Exposure to Macacine Alphaherpesvirus 1(BVirus) Procedure • OHS Information Sheet – Syringes, needles & syringe barrels – use & disposal at Monash University • OHS Risk Management Procedure • Risk Management Guidelines: Biologicals • OHS Induction and Training Procedure • OHS Training Requirements matrix
Related Legislation	• Australian Dangerous Goods Code v7.7 2020 • Australian Code for the Care and Use of Animals for Scientific Purposes 8th Edition, 2013 • Biosecurity Act 2015 • Biosecurity (Consequential Amendments and Transitional Provisions) Regulation 2016 • Code of Practice for Housing and Care of Laboratory Mice, Rats, Guinea Pigs and Rabbits (Vic) • Environment Protection Act 2017 • Environment Protection (Industrial Waste Resource) Regulations 2009 (Vic) • Gene Technology Act 2000 • Gene Technology Regulations 2001 • Occupational Health and Safety Act 2004 (Vic) • Occupational Health and Safety Regulations 2017 (Vic) • Prevention of Cruelty to Animals Act 1986 (Vic) • Prevention of Cruelty to Animals Regulations 2008 (Vic)
Category	Operational
Approval	Chief Operating Officer & Senior Vice-President 11 October 2021
Endorsement	Monash University OHS Committee 23 September 2021
Procedure owner	Health, Safety and Wellbeing Manager
Date effective	October 2021

Review date	2024
Version	7.1 (*Minor amendments effective 7 October 2022*)
Content enquiries	ohshelpline@monash.edu

DOCUMENT HISTORY

Version	Date Approved	Changes made to document
3	November 2012	Using Biologicals and Animals at Monash University Procedure, v.3
3.1	July 2015	Updated hyperlinks throughout to new OH&S website.
4	November 2015	1. Updated Abbreviation for Department of Agriculture 2. Changed DAFF Biosecurity to Department of Agriculture (DoA) throughout the document 3. Updated Definitions section to only include those that are specific to this procedure. Provided link to Definitions tool. 4. Updated Specific Responsibilities section to include only those specific to this procedure. Provided link to "OHS Roles, Committees and Responsibilities procedure". 5. Updated definition for Gene Technology (4.4) to reference Gene Technology Act (2000. 6. Updated references to legislation in Section 4.2. 7. Updated Sections 4.6 and 19.1 to reflect that Biosafety Officers should report any breach of compliance to the Research Compliance Officer, who will in turn notify the Institutional Biosafety Committee (IBC). 8. Updated section 11 to clarify the roles of the Research Compliance Officer and local Biosafety Officer regarding the purchase of biologicals. 9. Added requirements for the use of Clinismart bins in Section 17 – Waste disposal. 10. Updated records sections to reflect which records are retained by the Monash Research Office.
4.1	August 2017	1. Updated logos in header 2. Updated OHS Regulations to 2017
5	September 2018	1. Updated Abbreviations section 2. Updated terminology relating to quarantine throughout document to reflect changes to legislation, name of certification body and facility type. 3. Deleted Appendices II and III - Risk group listings and referred to relevant section of AS 2243.3 in section 5.1 of the procedure. 4. Updated "section 14 Waste disposal" to clarify correct use of Clinismart bins and bin liners for GMO and Biosecurity waste. 5. Updated section 15.1 to reflect that all incidents must be reported in SARAH and notified to the appropriate local safety personnel. 6. Clarified training requirements in section 13.3. 7. Minor wording and formatting changes and updates to hyperlinks.
6	March 2021	1. Changed Department of Agriculture and Water Resources (DAWR) to Department of Agriculture, Water and the Environment (DAWE) throughout the document. 2. Added section on Pregnancy and Breastfeeding. 3. Moved Risk Management section to start of document and included procurement requirements to align with ISO 45001. 4. Moved Importation of Biologicals to start of document, following Procurement section.

		5. Updated Waste section to clarify requirements for Biosecurity waste and GMO waste as well as recycling programs for these facilities. 6. Clarified approval requirements for the use of GM animals. 7. Clarified that the process for the certification of OGTR facilities is managed by the Monash Research Office. 8. Updated Animal Ethics training information.
6.1	July 2021	1. Updated certification logo in footer to ISO 45001 2. Updated the Standard to ISO 45001 under "Associated procedures" in the Governance table 3. Updated OHS Policy under 'Parent Policy' to OHS&W Policy
7.0	October 2021	1. Updated Zoonotic Diseases table in Appendix 1. 2. Updated section 14 to clarify requirements for the different waste streams in relation to point of use disposal, final disposal and treatment. 3. Added link to OREI Guidance on Waste treatment in 14.1.2. 4. Updated EPA legislation and Australian Dangerous Goods Code under 'Legislation mandating compliance' in Governance table.
7.1	October 2022	5. Updated name from Monash Research Office (MRO) to Office of Research Ethics and Integrity (OREI) throughout. 6. Updated references and links to waste disposal documents in Section 14.1.2. 7. Updated name of Procedure Owner to 'Health, Safety and Wellbeing Manager'. 8. Added 'Management of Suspected Exposure to Macacine Alphaherpesvirus 1(BVirus) Procedure' to associated procedures in Governance table.