Key Risk Area (KRA)

KRA 1.8 Gene Technology

1. Purpose

The University is committed to providing a safe and healthy work and study environment. This document provides guidance on how the University ensures that Gene Technology work undertaken by the University meets safety and compliance requirements.

2. Scope

This document applies to all health, safety and wellbeing activities of staff, students, visitors (including volunteers and contractors), Council members, and other persons interacting with the University of Newcastle (workers); the operations of staff of University aligned Research Centres and controlled entities; and all activities conducted by or on behalf of the University of Newcastle on and outside of the University's campuses.

3. Guidelines

3.1. Gene Technology Compliance

The Gene Technology Act 2000 prohibits all dealings with genetically modified organisms (GMOs) unless they are:

a) an exempt dealing;
b) a notifiable low risk dealing (NLRD);
c) included on the GMO Register;
d) an emergency dealing determination (EDD); or
e) licensed.

Details of approved dealings (except exempt) are publicly available on the GMO Record. All dealings with a genetically modified organism (GMO) need approval. Dealings include:

a) research;
b) manufacture;
c) production;
d) transportation;
e) destruction;
f) commercial release;

g) importation.

3.2. How to get approval to work with Genetically Modified Organisms (GMOs)

Obtaining and maintaining approval is a 3-step process.

Step 1 – Apply for approval

Organisation accreditation

Licenced dealings often require an organisation to be accredited. However, the OGTR recommends that, all organisations dealing with genetically modified organisms can benefit from accreditation. The University is an Accredited Organisation.

Institutional Biosafety Committees (IBCs)

IBCs play an important role in helping organisations comply with Australia's national gene technology regulatory scheme laws. They provide on-site assessment of low-risk contained dealings that do not need case-by-case consideration by the Regulator. IBCs also review licence applications for higher risk dealings before they are sent to the Regulator.
The University has an IBC which the University nominates as their IBC in their reporting to the OGTR.

Facility certification

Some dealings with GMOs must be undertaken in certified facilities.
The University has a number of certified physical containment facilities located at Callaghan, NIER, HMRI and Ourimbah campuses.
All workers who need to access certified facilities need to complete the OGTR Certified Facility Authorised Person Form to confirm they have read and will abide by the relevant guidelines the regulator has in place.

Approval to work with GMOs

All research and teaching activities involving genetically modified organisms need safety approval before they start. Anyone wishing to obtain, create, store or use a GMO at the University of Newcastle must create and submit a Safety Protocol in Tick@lab. The Safety Protocol will then be reviewed and assessed by the Institutional Biosafety Committee (IBC) in line with regulatory requirements. If the planned work is assessed by the IBC as falling under a dealing classification which requires a licence it will be submitted to the OGTR to undertake an assessment in order to approve under a licenced dealing or disprove.

Step 2 – Conduct dealings (if approved)

If approval is granted, the dealings with GMOs can be conducted. All conditions specified in the accreditation, authorisation, certification or licence must be observed. All dealings must be destroyed when they are completed or before they expire or a new application must be submitted if the work will be continuing or the GM material stored.

Step 3 – Ongoing regulatory compliance

The OGTRs focus is on the prevention of adverse outcomes before they can arise. They work with organisations to monitor and enforce compliance.

There are ongoing regulatory compliance obligations as below:

For organisations

- Submit annual report
- Report changes to key contacts
- Request changes to accreditation

For facilities

- Request changes to certification
- Comply with OGTR's routine monitoring

For GMO dealings

- Request changes to your licence
- Report non-compliance or unintended presence of GMOs
- Comply with OGTR's routine monitoring

3.3. Raising Concerns

Any member of the University community who has concerns about a breach of the KRA or the Gene Technology legislation should contact the Health, Safety and Wellbeing Team directly and lodge a report in the online Incident / Hazard Reporting System (AIMS).

When working with genetically modified organisms if there is an incident or unexplained symptoms or illness is experienced, seek medical attention and report the event using the online Incident / Hazard Reporting System (AIMS).

3.4. Enforcement

The University will enforce all conditions of their accreditation issued by the OGTR and requirements of the Gene Technology Act and Regulations related to certified facilities and approved dealings.

4. Definitions

In the context of the Health and Safety Management System Framework:

Accredited Organisation	Accreditation enables the Regulator to assess whether an organisation can effectively oversee work with GMOs through having appropriate: - governance arrangements - resources - internal processes. Accredited organisations must comply with the conditions of accreditation. Accreditation does not allow an organisation to conduct dealings with GMOs. The organisation must still obtain the correct approval or assessment before commencing. Before the Regulator can accredit an organisation, it must have access to an appropriately constituted Institutional Biosafety Committee. The Gene Technology Regulator requires organisations undertaking certain dealings with genetically modified organisms (GMOs) to be accredited. The Regulator also strongly encourages all organisations conducting dealings with GMOs to obtain accreditation. Find out more about organisation accreditation and how to apply
Authorised persons	Certified Facility Access is restricted to authorised persons (as described in Part B, conditions of the current version of the relevant OGTR Certified Facility Guideline).
Certified Facility	A PC facility which meets the certification requirements of the OGTR as outlined in the relevant OGTR facility certification guideline and AS/NZS 2243.3 and is certified by the Regulator or approved in writing by the Regulator. The Gene Technology Regulator certifies PC facilities to ensure that: - they meet appropriate standards for GMO containment - trained and competent staff carry out the procedures and practices. - all certified facilities must be inspected before applying for certification. - PC2, PC3 or PC4 certified facilities must be inspected annually. The University has the following types of certified facilities; - PC1 Certified facility - PC2 Certified Laboratory - PC2 Certified Plant Facility

	- PC2 Certified Animal Facility - PC2 Certified Constant Temperature Room Find out more about the facility certification process including the requirements for each type of facility and how to apply.
DNIR	A DNIR is a dealing not involving the intentional release of a GMO into the environment. These are dealings with GMOs in containment which do not meet the criteria for classification as exempt dealings or notifiable low risk dealings (NLRDs). Dealings with a GMO licensed as a DNIR must: - not involve release into the environment - be licensed by the Regulator. Schedule 3, Part 3 of the Regulations describes which dealings with GMOs cannot be authorised by NLRDs. These dealings need to be authorised by DNIR licences. DNIRs often involve genetically modified, disease-causing (pathogenic) organisms, or GMOs containing higher risk genes from pathogens or genes that: - encode toxins - confer a cancer-causing (oncogenic) modification or immuno-modulatory effect (changing the immune system).
DIR	A DIR is a dealing involving the intentional release of GMOs. These are dealings with GMOs which take place outside of containment. Most DIR licences issued have been for: - experimental field trials of GM plants (limited and controlled releases) - general/commercial releases of GM plants. The Regulator has issued some DIR licences for GMOs for medical or veterinary use, either for trial (limited and controlled release) or general/commercial release. The release of GM animals would also require a DIR licence.
Employer	Means the University of Newcastle (the University).
Executive Committee	Consisting of the Vice-Chancellor, the Deputy Vice-Chancellors, the Pro Vice-Chancellors, the Chief Operating Officer, Chief People and Culture Officer and the Chief Financial Officer, the University Secretary and the President of Academic Senate.
Exempt Dealing	Exempt dealings are dealings with GMOs that pose a very low risk. They cannot involve any release of a GMO into the environment, such as field trials or commercial releases. Schedule 2 of the Gene Technology Regulations 2001 lists dealings considered exempt. Parliament updates the list during legislative reviews of the Regulations. Typically, this is due to a submission from an Institutional Biosecurity Committee (IBC). Exempt dealings do not need a licence if the activity stays within specified criteria. Generally, an IBC will confirm if a dealing is exempt.

	The OGTR do not list exempt dealings on the GMO Record.
Gene Technology	Gene technology (also known as genetic engineering or genetic modification) provides ways to make changes to genes – the sets of instructions in the cells of all living creatures. There is a large amount of overlap between ‘gene technology’ and the newer term ‘synthetic biology’.
GMO	A genetically modified organism (GMO) is: - a plant, animal or other organism that has been modified using gene technology - an organism that has inherited modified traits from a GMO.
GMO Dealing	A dealing is an interaction with a GMO. The Gene Technology Act 2000 defines a dealing as meaning: - conduct experiments with the GMO - make, develop, produce or manufacture the GMO - breed the GMO - propagate the GMO - use the GMO in the course of manufacture of a thing that is not the GMO - grow, raise or culture the GMO - import the GMO - transport the GMO - dispose of the GMO - possess, supply or use the GMO for the purposes of, or in the course of, any of the above. There are a number of dealing classifications (exempt, NLRD, DNIR, DIR, inadvertent dealings). Learn more about the types of dealing (also listed below) and their requirements.
GMO Record	The Record of GMO Dealings, or GMO Record, provides the community with access to information about GMOs in Australia. The GMO Record has been operating since 2001. It's an important part of the transparency of GMO regulation. The GMO Record includes information on all dealings, except exempt dealings.
IBC	Institutional Biosafety Committee (IBCs) play an integral role in assisting compliance with Australia’s national gene technology regulatory scheme laws. IBCs evaluate low-risk contained dealings that do not require case-by-case consideration by the Regulator. They also provide a quality assurance mechanism by reviewing the information applicants submit to the Regulator. IBCs are not responsible for the conduct of organisations that they assist. They help with identifying and managing risks with GMOs without attracting liability for damages.

	Accredited organisations may have multiple IBCs specialising in different fields of expertise. Organisations may also seek advice from IBCs established by another organisation. Learn more about the role of IBCs. Further information on the IBC is found in KRA 1.2 Biological Safety
Inadvertent dealings	It is possible to come into possession of a GMO without realising or intending to. If this happens, all further dealings with the GMO, including destruction, need an authorisation.
Leader / Supervisor	Any member of the University who is responsible for supervising staff and/or undergraduate or postgraduate students and/or for leading research projects.
Licenced Dealing	DIR or DNIR
NLRD	A notifiable low risk dealing (NLRD) is an activity with GMOs that is: - undertaken in containment, in an appropriate facility certified by the Regulator or approved in writing by the Regulator - assessed as posing low risk to the health and safety of people and the environment provided organisation meets certain risk management conditions. Schedule 3 of the Gene Technology Regulations 2001 (the Regulations) specifies the types of dealings with GMOs classified as NLRDs. An Institutional Biosafety Committee (IBC) must assess a dealing as an NLRD before it can be undertaken. Details of NLRDs are publicly available in the GMO record. You must conduct NRLDs: - as described in the IBC Record of Assessment (RoA) - using people with appropriate training and experience - within a facility specified in the RoA. You must transport, store and dispose of GMOs according to the Regulator's guidelines. The Regulator may specifically approve alternate conditions for a particular NLRD. An NLRD RoA is only valid for 5 years. Each dealing must be assessed every 5 years to ensure they still meet the requirements to be conducted as an NLRD.
Nominated CEO or equivalent	For the accreditation of the University with the OGTR the Deputy Vice Chancellor (Research & Innovation Division) is the nominated CEO or equivalent
OGTR	Office of the Gene Technology Regulator
Organisation Primary Contact Officer	At the University of Newcastle there are two roles in the HSW Team, Resources Division who act as Primary Contacts with the OGTR

PC Level	Physical Containment Level of a facility (PC1 to PC4) satisfies the criteria in AS/NZS 2243.3; and The OGTR classifies physical containment (PC) facilities based on: - the structural integrity of buildings - what equipment is used - how facility workers handle GMOs. PC level 1 (PC1) facilities are used to contain organisms posing the lowest risk to human health and the environment. PC level 4 (PC4) facilities provide the most secure and stringent containment conditions. Further information on PC facilities is found in KRA 1.2 Biological Safety
Risk Group	Organisms are classified into a risk group (RG1 to RG4) that satisfies the criteria in AS/NZS 2243.3 Further information on Biological Risk Groups is found in KRA 1.2 Biological Safety
Worker	Includes an employee, conjoint, student on work experience, contractor, sub-contractor, and volunteer. A person is a worker if the person carries out work in any capacity for the University or another person conducting a business or undertaking, including work as: (a) an employee, or (b) a contractor or subcontractor, or (c) an employee of a contractor or subcontractor, or (d) an employee of a labour hire company who has been assigned to work in the person's business or undertaking, or (e) an outworker, or (f) an apprentice or trainee, or (g) a student gaining work experience, or (h) a volunteer, or (i) a person of a prescribed class.
Workplace	Means any recognised or defined area, location or vehicle where workers carry out their work.

5. Responsibilities

A comprehensive list of health, safety and wellbeing responsibilities is provided in HSG 1.2 Roles and Responsibilities Guideline.

Specific responsibilities under this Guideline include:

Nominated CEO or equivalent

- Must ensure the organisation complies with the conditions of the accreditation, certifications, approved dealings in accordance with the Gene Technology Act and Regulations

Infrastructure and Facility Services (IFS)

- Ongoing servicing and maintenance of University certified facilities and related fixed infrastructure and fittings included; autoclaves, backflow prevention, pest control, handwash sinks, eyewash station;
- Ensure any maintenance or repair work to be conducted in the facility is discussed with the Organisation Primary Contact Officer/s to determine if it requires notification of a minor works or application for a variation to the certification to the OGTR before the work proceeds.

Certified Facility Owner- if not University of Newcastle (e.g. HMRI)

- Ongoing servicing and maintenance of facilities certified under the University's accreditation including related fixed infrastructure and fittings including autoclaves, backflow prevention, pest control, handwash sinks, eyewash station;
- Ensure any maintenance or repair work to be conducted in the facility is discussed with the Organisation Primary Contact Officer/s to determine if it requires notification of a minor works or application for a variation to the certification to the OGTR before the work proceeds.

Supervisors and Leaders

- Ensure workers, visitors and contractors who report to them are aware of this KRA;
- Ensure workers, visitors and contractors who report to them who are planning to work or working with GMOs or Gene Technology complies with this KRA;
- Ensure all University Gene Technology work planned by workers, visitors and contractors who report to them have been approved as outlined in this KRA
- Ensure all University Gene Technology work is conducted in compliance with the conditions of the University accreditation and in accordance with the facility certifications and OGTR guidelines related to working with GMOs outlined in this KRA
- Ensure all dealings relating to Gene Technology and Genetically Modified Organisms has current safety approval which includes the IBC assessment before it is commenced.
- Ensure all users of certified facilities are authorised persons and have completed the authorised person training which includes Part B and Part C of the relevant OGTR Guideline for certification of Physical Containment Facilities with records held locally.
- Report issues of non-compliance of workers in accordance with the KRA;

- Support suitable representation of workers who report to them as members of the Institutional Biosafety Committee reflecting the volume of Gene Technology and Biological work conducted by their workers.

Institutional Biosafety Committee

- Assist the University to meet its compliance responsibilities with Australia's national gene technology regulatory scheme laws.
- Evaluate low-risk contained dealings that do not require case-by-case consideration by the Regulator.
- Provide a quality assurance mechanism by reviewing the information applicants submit to the Regulator.

Health, Safety and Wellbeing Team (Roles that include Organisation Primary Contact Officer with OGTR)

- Monitor the effectiveness of this KRA and support its implementation;
- Implement and maintain procedures to support this KRA;
- Provide training programs for workers to support this KRA.
- Manage the administration relating to the Universities accreditation, certifications and approved dealings to ensure they remain current
- Service the Institutional Biosafety committee (IBC) and administer the Safety review system where all planned Gene Technology work is assessed and approved (other than licenced dealings which are then submitted to the OGTR for approval) before it commences
- Conduct certification inspections and manage facility certifications
- Conduct annual inspections of certified PC2 facilities and inspect certified PC1 facilities as required
- Manage compliance for certified facilities in relation to suspensions, surrenders and minor works
- Ensure NLRDs are notified to the OGTR as required under the Gene Technology legislation
- Ensure an annual report is submitted to the OGTR
- Review any reports relating to non-compliance including breaches of containment and notify the OGTR as required when and as required. by the Gene Technology legislation

Local Safety Contact Person

- Assist Supervisors and leaders to ensure workers, visitors and contractors who are planning to work or working with GMOs or Gene Technology complies with this KRA;
- Assist Supervisors and leaders to ensure all University Gene Technology work is conducted in compliance with the conditions of the University accreditation and in accordance with the facility certifications and OGTR guidelines related to working with GMOs outlined in this KRA
- Ensure all users of certified facilities are authorised persons and have completed the authorised person training which includes Part B and Part C of the relevant OGTR Guideline for certification of Physical Containment Facilities with records held locally.
- Report issues of non-compliance of workers in accordance with the KRA
- Ensure any planned maintenance or repair work to be conducted in the facility is discussed with the Organisation Primary Contact Officer/s to determine if it requires notification of a minor works or application for a variation to the certification to the OGTR before the work proceeds.

Workers

- Staff members, employees, students, visitors, contractors and workers must comply with reasonable health and safety instructions, policies and procedures including this KRA; and
- Only conduct work on dealings relating to Gene Technology and Genetically Modified Organisms that have Safety Approval and comply with any associated conditions.
- Complete the authorised person training which includes Part B and Part C of the relevant OGTR Guideline for certification of Physical Containment Facilities to become an authorised person before commencing any work in a certified facility.
- Report any Gene Technology safety or compliance issues to supervisors, their leader or the Health, Safety and Wellbeing Team, in addition to lodging a report in the online Incident / Hazard Reporting System (AIMS).

6. References & Related Documents

The following documentation is referenced in, or applicable to this Key Risk Area:

HSG 1.2 Roles and Responsibilities

KRA 1.2 Biological Management

Institutional Biosafety Committee Terms of Reference

University of Newcastle OGTR Certified Facility Authorised Person Form

NSW Work Health and Safety Act and Regulations

The Gene Technology Acts and Regulations

Office of the Gene Technology Regulator (OGTR)

OGTR Facility Certification Guidelines

OGTR Guidelines for the Transport, Storage and Disposal of GMOs

AS 2243.1:2021 Safety in Laboratories, Part 1: Planning and operational aspects

AS/NZS 2243.3 Safety in Laboratories, Part 3: Microbiological safety and containment

AS/NZS 2243.6 Safety in Laboratories, Part 6: Plant and equipment aspects

7. Amendment History

Version	Date of Issue	Approval	Section(s) Modified	Details of Amendment
1	October 2023	CPCO	All	Original version which combines existing information on the University and OGTRs webpages. All sections reviewed for legal compliance.

8. Appendices

Nil