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Superseded Documents	HS330 Gene Technology Procedure v3.2, approved 30 April 2014 by Director, UNSW Safety and Sustainability		
File Number	2015/30222		
Associated Documents	<ul style="list-style-type: none"> <li>• Australian Code for the Responsible Conduct of Research 2007</li> <li>• Gene Technology Act 2000</li> <li>• Gene Technology Regulations 2001</li> <li>• National Framework of Ethical Principles in Gene Technology 2012</li> <li>• UNSW Research Code of Conduct</li> <li>• UNSW Animal Research Ethics Procedure</li> <li>• UNSW Procedure for Handling Allegations of Research Misconduct</li> <li>• UNSW Biosafety Procedure</li> </ul>		
<b>Version</b>	<b>Authorised by</b>	<b>Approval Date</b>	<b>Effective Date</b>
1.0	Vice-President and Deputy Vice-Chancellor (Research)	31 July 2015	1 August 2015

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## 1. Purpose and Scope

This document sets out the responsibilities and authorities governing gene technology research and its ethical considerations in accordance to the requirements of the *Gene Technology Act 2000* (henceforth referred to as the *Act*) and the *Gene Technology Regulations 2001* (the *Regulations*) and other relevant codes and legislation. The content of the document applies to all staff and research trainees at UNSW and affiliated centres and institutes involved in gene technology research in Australia and overseas.

## 2. Preamble

Gene technology presents exciting opportunities for health and scientific research such as cancer research through oncogenic modification to explore tumour formation in genetically modified organisms (GMOs). At the same time, development and use of gene technology and GMOs involves real and perceived levels of risk to people and the environment. Gene technology may result in harm to the health and safety of people or to the environment. At UNSW, the risks involving gene technology research are evaluated by the UNSW Gene Technology Research Committee (GTRC) and, where required, by the Federal Office of the Gene Technology Regulator (OGTR; the Regulator), on the grounds that reduction of possible harm to the health and safety of people and the environment is at the core of research activities.

## 3. Definitions

The following definitions apply to this Procedure and associated Guidelines:

**Advantage:** in relation to an organism that is genetically modified, means a superior ability in its modified form, relative to the unmodified parent organism, to survive, reproduce or otherwise contribute to the gene pool.

**Dealing:** includes (a) conducting experiments with, (b) make, develop, produce or manufacture, (c) breed, and (d) propagate a GMO, (e) use a GMO in the course of manufacture of a thing that is not a GMO, and (f) grow, raise or culture, (g) import, (h) transport and (i) dispose of a GMO; this includes the possession, storage, supply or use of a GMO for the purposes of, or in the course of, a dealing.

**Exempt dealing:** is a category of dealings with GMOs that have been assessed over time as posing a very low risk (i.e. contained research involving very well understood organisms and processes for creating and studying GMOs). The only legislative requirement for exempt dealings is that they must not involve an intentional release of a GMO into the environment. Exempt dealings are described in Parts 1 & 2 of Schedule 2 of the *Gene Technology Regulations 2001*.

**Gene technology:** any technique for the modification of genes or other genetic material, excluding (a) sexual reproduction, (b) homologous recombination and (c) any other technique specified in the *Regulations*.

**Genetically modified organism (GMO):** includes (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, or (c) anything declared by the *Regulations* to be a GMO, or that belongs to a class of things declared by the *Regulations* to be GMOs.

**Notifiable Low Risk Dealing (NLRD):** a dealing with GMOs that has been assessed as posing low risk to the health and safety of people and the environment provided certain risk management conditions on containment, transportation, storage and disposal are met. NLRDs are described in Parts 1 & 2 of Schedule 3 of the *Gene Technology Regulations 2001*.

**Oncogenic modification:** a genetic modification capable of contributing to tumour formation, including modifications that cause at least one of the following: (a) defects in DNA proofreading and repair, (b) defects in chromosome maintenance, (c) defects in cell cycle checkpoint mechanisms, (d) uncontrolled cell proliferation, (e) resistance to apoptosis, and/or (f) cellular immortalisation.

**Physical containment (PC) facility:** a facility certified by the Regulator to a specific containment level (PC1-PC4) to protect the health and safety of people and the environment.

**Physical containment (PC) level:** followed by a numeral, is a specified containment level (PC1-PC4) under guidelines made by the Regulator, under section 90 of the *Act*, for the certification of facilities.

**Regulator:** the Office of the Gene Technology Regulator (OGTR).

## 4. Regulatory Environment

UNSW is an Accredited Institution with the Regulator in accordance to the requirements of the *Act*. The Vice-Chancellor, as Head of the Establishment, has delegated the Deputy Vice-Chancellor (Research) to oversee gene technology research at UNSW. The DVC(R) has delegated responsibilities of oversight to the UNSW Australia Gene Technology Research Committee (GTRC) according to its terms of reference and according to the requirements of the *Act* and *Regulations*.

All gene technology research above the level of Exempt Dealings are reviewed by the GTRC and approved by the DVC(R) and, where required, by the Regulator, prior to the commencement of the research. Facilities for dealings above the level of Exempt Dealings are inspected by the GTRC and recommended for certification by the Regulator prior to commencement of gene technology research within the facilities. Any proposed changes to approved GTRC protocols and facilities are reviewed by the GTRC and approved by the DVC(R) and, where required, by the Regulator. Exempt dealings are submitted to the GTRC for noting only.

Research involving genetically modified higher-order invertebrate or vertebrate animals or gene technology research using higher-order invertebrate or vertebrate animals requires additional review by the UNSW Australia Animal Care & Ethics Committees (ACECs) and approval by the DVC(R). Additional permit requirements apply to the import or export of genetically modified material or animals.

## 5. Principles of Gene Technology Research at UNSW

The University recognises the risk criteria in proposed dealings with GMOs outlined in the *Act* and *Regulations* and the potential harmful consequences to people and the environment posed by gene technology research. Harm to the health and safety of people includes, for example, toxicity, allergenicity, disease or injury, and harm to the environment can involve toxicity to other organisms, loss of biodiversity or disruption or adverse effects on the biotic environment through selective advantage of GMOs, or degradation of the abiotic environment.

The framework for gene technology research at UNSW is based on the potential levels of harm to people and the environment and taking into account the appropriate levels of containment and safety procedures in the use of the parent organism and changes due to gene technology. The University also recognises that our knowledge of true risks is constrained by rapidly developing technology and at the same time that some risks may be perceived rather than real. Appropriate levels of risk in gene technology research are determined on an on-going basis by the DVC(R) in consultation with the GTRC and based on the evolving requirements of the *Act* and *Regulations*.

## 6. University Gene Technology Research Committee

### 6.1 Scope

The UNSW GTRC shall act in relation to:

- UNSW and its affiliated organisations including those for which Affiliation Agreements are in force in respect of gene technology matters and the role of the UNSW GTRC; and
- All research, teaching or other activity that involves dealings with genetically modified organisms as defined under the relevant *Act* and the *Regulations*.

In addition to the responsibilities accorded under the Act, the Regulations, Guidelines and the Affiliation Agreements, the UNSW GTRC shall provide advice to the Vice Chancellor of UNSW (or delegated officer) in relation to any biological hazard generated in the course of, or relevant to, teaching, research or other activity involving GMOs within UNSW or its affiliated organisations.

## 6.2 Terms of Reference

Under its terms of reference, the UNSW GTRC is charged with the following responsibilities:

1. Assist project supervisors to identify, in accordance with the *Gene Technology Act 2000* and the *Gene Technology Regulations 2001*, proposed dealings involving the use of genetically modified organisms as Notifiable Low Risk Dealing (NLRD) or a dealing requiring licensing by the Regulator. The assessment and review of dealings involving GMOs including: (i) consideration of the actual and potential risks to the health and safety of people and the environment; (ii) the competence of the personnel using GMOs and that the people using GMOs have the appropriate experience skills and training to work with GMOs; and (iii) there is the appropriate level of containment of the laboratory facilities used in working with GMOs.
2. In respect of proposed dealings requiring licensing by the Regulator, provide its assessment of the dealing on the OGTR licence application form and assist with the submission of the application to the Regulator and communicate the outcome back to the project supervisors.
3. For research above the level of Exempt Dealings inspect and recommend for certification to the Regulator, physical containment facilities before they are used for work involving GMOs.
4. Conduct annual inspections of all OGTR-certified facilities at and above level PC2 and oversee the follow-up of corrective actions.
5. Receive reports of incidents, including spills and unintentional release of GMOs, recommend actions for improvement or remediation, and report the incidents to regulatory authorities as required.
6. Provide advice to the Vice Chancellor of UNSW (or delegated officer) in relation to any biological hazard generated in the course of, or relevant to, teaching, research or other activity involving GMOs within UNSW or its affiliated organisations.
7. Forward any complaints and allegations of research involving GMOs which may involve deviations from the UNSW Code for the Responsible Conduct of Research to the DVC(R).
8. Report to the Regulator in accordance with the obligations and responsibilities under the *Act, Regulations and Guidelines for Accreditation of Organisations* issued by the Regulator.
9. Report on a regular basis to the DVC(R) and annually to University Council on its activities and compliance with its terms of reference.

## 6.3 Membership

The UNSW GTRC comprises a minimum of six people and has the collective expertise to competently assess and provide advice on the work undertaken by the University and its affiliated organisations. Roles and responsibilities may be combined in the same person where appropriate.

Committee members, including the Presiding Member, are appointed by the DVC(R) for a period of 3 years, with the possibility for renewal for another three years. The DVC(R) can terminate membership at any time. The Committee may make recommendations to the DVC(R) regarding the continuation of any member. The DVC(R) nominates a Deputy Presiding Member from the GTRC membership. The Deputy Presiding Member will act in Presiding Member's absence or where the Presiding Member has a conflict of interest.

All members are appropriately indemnified by the University to fulfil their role on the GTRC.

## 6.4 Composition

The UNSW GTRC is composed of the following membership:

- The Presiding Member.
- At least four persons who have a combined expertise in the research disciplines overseen by the GTRC. These disciplines may include molecular biology, microbiology, genetics, virology, immunology, oncology, biochemistry, epidemiology, plant biotechnology or bio-containment/ biosafety engineering, and infection control.
- At least one lay person external to the University and not involved in research using gene technology to reflect the views of the wider community.
- One representative of UNSW Health & Safety as the Biosafety Coordinator.

## 6.5 Conflict of Interest

The following arrangements are in place to deal with conflicts or potential conflicts of interest as defined in the OGTR *Explanatory Information on the Guidelines for Accreditation of Organisations* 2013:

- Members declare to the Presiding Member or Deputy, at the earliest opportunity, any potential conflict of interest in any matter that is presented to the UNSW GTRC for assessment.
- All declarations of conflict of interest are recorded in the minutes of the meeting at which the declaration is made.
- The member who has declared a conflict of interest is excluded from the deliberations and assessment of the matter by the UNSW GTRC.
- If a sufficient number of members with relevant qualifications and experience are not available, the final recommendation for a proposal is postponed until the views of additional members have been sought or until the next meeting of the UNSW GTRC.

## 6.6 Attendance at Meetings

Members are selected onto the UNSW GTRC due to their relevant expertise and as such, must be present at meetings of the UNSW GTRC where their expertise is required in respect of assessments of particular proposed dealings. If members cannot attend meetings where their expertise is required, they will notify the Secretary of the GTRC as soon as possible.

Although membership to the UNSW GTRC is voluntary, members are deemed to have vacated office if they are absent without leave for three consecutive meetings. The UNSW GTRC records absences and apologies are lodged by a member who is unable to attend a meeting. The UNSW GTRC may consider granting leave of absence when a member has missed two consecutive meetings and seeks leave (in writing) to miss a third meeting giving reasons for each absence. Leave of absence may be granted for one or more meetings at the discretion of the Presiding Member of the UNSW GTRC. The Presiding Member will report this to the DVCR.

The UNSW GTRC may co-opt and invite non-members to meetings to provide expert advice outside the scope of knowledge of the Committee. Such invitees will not vote in any decisions of the UNSW GTRC.

## 6.7 Quorum and Decision Making Process

The decisions by the UNSW GTRC are made by consensus as recommendations to the DVC(R) at quorate meetings, where quorum consists of at least 50% of members present. Out of session decisions are ratified at the next quorate meeting.

## 7. Institutional Biosafety Coordinator

As an *ex officio* member of the UNSW GTRC, the UNSW Biosafety Coordinator advises the GTRC and the University's researchers on health and safety regulations as relevant to gene technology research and GMO containment. The Biosafety Coordinator provides specialist



strategic advice to the GTRC on how to minimise risks of gene technology research to human health and the environment and is a point of contact in emergencies where there is danger to humans or the environment.

The Biosafety Coordinator ensures that University health and safety processes are recognised and followed as part of gene technology research and integrated with GTRC processes. The UNSW Biosafety Coordinator works with the GTRC to provide gene technology and containment facility training as required by the Regulator and ensures that training needs are integrated with general biosafety requirements.

## 8. Facility Certification and Inspection

Researchers are responsible to ensure that, as a minimum, all Exempt dealings are conducted in PC1-compliant facilities. Facilities for proposed NLRD, DNIR and DIR research require certification by the Regulator. The GTRC is responsible for inspecting and recommending facilities to the Regulator for certification.

Upon successful certification the GTRC conducts annual inspections and communicates with the Regulator about any proposed structural changes to certified facilities. Any items identified by the GTRC deemed non-compliant with certification conditions must be addressed by the Head of the facility within a specified time frame and the Regulator is notified as required. The DVC(R) may suspend gene technology research at any time should the facility be found non-compliant with certification conditions.

## 9. External and Multi-centre Gene Technology Research

UNSW researchers do not need to seek review by the UNSW GTRC if the research is conducted elsewhere and an external GTRC accredited by the Regulator or by the appropriate overseas authority provides the review, approval and monitoring of the research according to the *Act* and *Regulations*. However, evidence of the external review and approval must be provided by the lead UNSW researcher to UNSW prior to the commencement of the research or participation in an external project as requested on the UNSW Gene Technology Research website.

Gene technology projects across multiple institutions need to be approved by the responsible GTRC or equivalent biosafety committee, where each committee is responsible for approving and monitoring the research at its institution. Participating committees may share documentation to raise awareness of all aspects of the research and potential implications of cumulative risks to humans or the environment.

The University reserves the right to place conditions on involvement or refuse involvement in external projects by its researchers should approved proposals not confirm to the requirements of the *Act* and *Regulations*, other relevant legislation or potentially expose the University to undue risk.

## 10. Monitoring of Research and Adverse Events

Gene technology research approved by UNSW is monitored by the University and its delegated bodies through mechanisms described in the *Act* and *Regulations*, including annual and final reports for each approved project, internal and external audits of compliance with the approved protocol, and site visits and interviews with investigators and laboratory staff. The University may suspend or withdraw approval for gene technology research where it is reasonable to believe that continuation of the research project may compromise compliance with legislation.

Chief investigators are required to monitor research according to the approved protocol and report unexpected adverse events to the GTRC Support Officer as soon as possible in accordance to the emergency instructions on the UNSW Gene Technology Research [website](#). This includes any unintentional release of Exempt Dealings even though they do not require GTRC review. The Biosafety Coordinator needs to be informed as soon as possible where

there is possible risk to human safety involved. The Committee may request additional monitoring and other actions as deemed appropriate.

Issues identified during monitoring or adverse event reporting which may possibly involve breaches of the UNSW Research Code of Conduct are immediately referred to the DVC(R) and dealt with according to the UNSW Procedure for Handling Allegations of Research Misconduct.

## 11. Complaints and Grievances

UNSW has established a complaints and grievances mechanism for UNSW personnel, students and persons external to the university. This process allows the voicing of concerns regarding animal research and the ethical review process.

Complaints about the conduct of research by UNSW staff and research trainees should be directed to the DVC(R). Allegations involving possible breaches of the *Australian Code for the Responsible Conduct of Research* are dealt with in accordance with the *UNSW Research Code of Conduct*.

Grievances about GTRC review and processes by UNSW staff and students should be addressed to the Director of RECS.

## 12. Additional Operating Guidelines

Gene Technology Research operating guidelines in support of this Procedure, such as rulings on record keeping, containment, competency and standard operating procedures for working with genetically modified organisms are approved by the DVC(R) and displayed in their most current form on the gene technology research [website](#).

## 13. Review & History

Version 1.0 of this Procedure was developed to facilitate compliance with the *Gene Technology Act 2000* and the *Gene Technology Regulations 2001*. The Procedure is scheduled for review every three years.

Version	Authorised by	Approval date	Effective Date	Sections modified
1.0	Vice-President and Deputy Vice-Chancellor (Research)	31 July 2015	1 August 2015	New document.