Biosafety in Research Vice-Chancellor's Directive

Abstract

The purpose of this Directive is to inform researchers of their responsibilities in relation to dealing with biological hazards while undertaking research or teaching at UTS.

Dates	Directive approved Directive takes effect Directive is due for review (up to five years)	20/02/2014 20/03/2014 03/2019
	Amendment approved Amendment takes effect	15/10/2014 19/08/2016
Approved by	Vice-Chancellor	
	Latest amendment: Council, COU/14-5/106 (see change history for details)	
Implementation Officer	Director, Research and Innovation Office	
Relevant to	Researchers at UTS, including staff and students	
Related documents	Application to certify facilities (including guidelines and forms) Australian Code for the Responsible Conduct of Research (the Code) Australia/New Zealand Standard: Safety in laboratories, Part 3: Microbiological safety and containment (AS/NZS 2243.3) Australia/New Zealand Standard: Safety in laboratories, Part 4: Ionizing radiations AS/NZS 2243.4 Code of Conduct Containment of Exempt Dealings Ethical Conduct of Research Involving Animals Vice-Chancellor's Directive Ethical Conduct of Research Involving Human Participants Vice-Chancellor's Directive Guidelines for Accreditation of Organisations Guidelines for the Transport, Storage and Disposal of GMOs Office of the Gene Technology Regulator (OGTR) Responsible Conduct of Research Policy	

	Sustainability Policy United Nations Economic Commission for Europe – Globally Harmonized System of Classification and Labelling of Chemicals (GHS)
Legislation	Gene Technology Act 2000 (Cwlth) Gene Technology Regulations 2001 (Cwlth) National Health Security Act 2007 (Cwlth) National Health Security Regulations 2008 (Cwlth) Radiation Control Act 1990 (NSW) Radiation Control Regulation 2013 (NSW) Work Health and Safety Act 2011 (NSW) Work Health and Safety Regulation 2011 (NSW)
File number	UR14/347

Contents

1. Purpose

UTS is committed to providing a safe and healthy workplace for students, staff and visitors, and adopting a socially responsible approach towards protecting and sustaining the environment. It aims to be at the forefront of environment, health and safety practice in higher education.

The purpose of this Directive is to outline the responsibilities of researchers that use or engage with biological hazards (genetically modified organisms, pathogens, ionising radiation and cytotoxic substances) in their research. This Directive seeks to ensure that work with biological hazards is subjected to a level of external review to ensure that the risks associated with the use of the hazard or agent have been assessed, and that the risk management strategies implemented (or proposed) are appropriate.

This Directive also highlights the function of the UTS Institutional Biosafety Committee (UTS IBC) and the University's requirements to ensure compliance with government legislation.

This Directive is supplementary to, and should be read in conjunction with, the UTS Responsible Conduct of Research Policy.

2. Scope

This Directive applies to any person conducting research and teaching involving the use of, or interaction with, biological hazards under the auspices of UTS, whether that person is a staff member, student or non-staff member. This Directive also applies to UTS centres and institutes. Research in this context is understood broadly to encompass both funded and unfunded research.

This Directive is implemented by the Director, Research and Innovation Office. Day-to-day advice regarding matters covered by this Directive can be sought from the Ethics Secretariat (restricted access: UTS login only).

3. Definitions

The following definitions define terms that are specific to this Directive. These are in addition to terms defined in Schedule 1, Student Rules, and those provided in the Responsible Conduct of Research Policy.

Accredited organisation means an organisation accredited by the Gene Technology Regulator under section 92 of the Gene Technology Act 2000 (Cwlth).

Biological hazards for the purposes of this Directive, means genetically modified organisms (GMO), pathogens, ionising radiation and cytotoxic substances, as determined by the UTS IBC.

Chief investigator is the person who takes responsibility for the conduct of the research on day-to-day basis.

Cytotoxic substances for the purposes of this Directive, cytotoxic substances are known to be highly toxic and are considered to be either:

- carcinogens
- mutagens, or
- reproductive toxicants

as defined by the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). The Safety Data Sheet (SDS) for the substance will identify if it is classified as one of these categories.

Dealing or **deal with** a GMO, (as defined in the Gene Technology Act) means the following:

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

and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned above.

Genetically modified organism (**GMO**) (as defined in the Gene Technology Act) means:

a. an organism that has been modified by gene technology, or
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 genetically modified organism, or that belongs to a class of things declared by the Regulations to be genetically modified organisms

but *does not* include:

d. human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy
e. an organism declared by the Regulations not to be a genetically modified organism, or that belongs to a class of organisms declared by the Regulations not to be genetically modified organisms.

Gene technology (as defined in the Gene Technology Act) means any technique for the modification of genes or other genetic material. It *does not* include:

a. sexual reproduction
b. homologous recombination
c. any other technique specified in the Regulations for the purposes of this paragraph.

Ionising radiation means particulate (alpha or beta) or electromagnetic (gamma or x) radiation capable of producing ions directly or indirectly in its passage through matter. Ionising radiation may be produced by an irradiating apparatus (for example, an x-ray unit) or by a radioactive substance or radionuclide (for example, Phosphorus-32 or Carbon-14). This is also defined in the Radiation Control Act 1990 (NSW).

Office of the Gene Technology Regulator (**OGTR**) means the Office established within the Australian Government Department of Health to provide administrative support to the Gene Technology Regulator in the performance of the Regulator's functions under the Gene Technology Act.

Radioactive substance, as defined by the Radiation Control Act (Part 1, section 4), means any substance that emits ionising radiation spontaneously. Most commonly, radioisotopes (radioactive chemical tracers) are employed as tracers in biological experiments (for example, [14C]-glucose).

Regulations means the Gene Technology Regulations 2001 (Cwlth).

Regulator means the Gene Technology Regulator, the statutory office holder responsible for administering the national regulatory system for gene technology as set out in the Gene Technology Act.

Transport is described by the Regulator as meaning 'to carry or convey from one place to another'.

UTS Institutional Biosafety Committee (**UTS IBC**) means the Vice-Chancellor's committee established to ensure that all research and teaching undertaken by UTS staff and students is conducted in a safe manner. The establishment of the UTS IBC fulfils the requirements of the University's accreditation by the Regulator under section 92 of the Gene Technology Act.

Pathogens mean microorganisms that can cause human, plant or animal disease (bacteria, parasites, fungi or viruses). For the purposes of this Directive, all microorganisms are considered to be potential pathogens.

Risk categories

Risk categories of microorganisms and the corresponding Physical Containment (PC) Levels as per Australia/New Zealand Standard: Safety in Laboratories, Part 3: Microbiology AS/NZS 2243.3 are as follows:

Risk Group 1: Physical Containment Level 1 (PC1 containment)

- Low individual risk and community risk
- Microorganism unlikely to cause human, plant or animal disease

PC1 requirements

- Special containment equipment is not necessary
- Work on open bench
- General laboratory safety requirements

Risk Group 2: Physical Containment Level 2 (PC2 containment)

- Moderate individual risk, limited community risk
- Pathogen can cause human, plant or animal disease
- Unlikely to be a hazard to laboratory workers
- Prophylaxis and treatment available
- Risk of spread limited
- Examples include E. coli (except genetically crippled strains), Enterobacter sp., Shigella sp., Staph. aureus

PC2 requirements

This level of containment is applicable to work involving indigenous microorganisms from Risk Group 2 that may be associated with disease of moderate severity. With good microbiological practice, work with these agents may be carried out on the open bench, provided that the potential for producing aerosols is low. If the aerosol risk is high (see Aerosol risks definition (and corresponding Physical Containment level) below), primary containment equipment shall be used.

Note: Work with some Risk Group 2 microorganisms may require prior vaccination of staff.

All recombinant DNA experiments require at least PC2 containment. Recombinant DNA techniques include any experiment involving the construction and/or propagation of viroids, viruses, cells or organisms of novel genotype produced by genetic manipulation which are either unlikely to occur in nature or likely to pose a hazard to public health or to the environment.

Aerosol risks: aerosols are generated from the following laboratory operations: vortexing, sonicating, homogenising, centrifuging or vigorous shaking or mixing of cultures in open vessels; also from spillage of high-titre cultures or opening containers of infectious material whose internal pressure is different from ambient pressure.

Primary PC2 containment requires:

- biological hazard and restricted access signs on entrance doors and procedures requirements. These will be provided by the UTS IBC once the laboratory has been certified as PC2.

- gloves, goggles, closed footwear and laboratory coats to be worn. Gloves should be discarded along with other laboratory waste (which is to be autoclaved).
- for the control of aerosols, a Class I or II biological safety cabinet
- hand-washing basins and eyewash stations
- disinfectants for decontamination
- centrifuges with sealed rotors or sealed tubes and bottles
- no food or drink in the laboratory
- mouth pipetting is prohibited
- cultures to be identified, dated and stored appropriately
- the dispersal of spores from fungal cultures to be minimised by sealing petri dishes with tape and using dedicated incubators
- laboratory personnel to be trained in handling pathogens. Restricted access to the laboratory and doors normally closed.
- all clinical specimens to be regarded as potentially hazardous
- any viable organisms being transported between laboratories or to an autoclave facility need to be in a second sealed and unbreakable container
- glassware to be chemically disinfected or autoclaved

Risk Group 3: Physical Containment Level 2 (PC3 containment)

- High individual risk, limited community risk
- Pathogen may cause serious human or animal disease
- Prophylaxis and treatment available
- Examples include Bacillus anthracis, Mycobacterium bovis, Rickettsia sp., Yersinia pestis.

Note: UTS *does not* currently have the facilities to contain Risk Group 3 microorganisms.

Risk Group 4: Physical Containment Level 2 (PC4 containment)

- High individual and community risk
- Life-threatening human or animal disease
- Serious hazard to laboratory workers
- Readily transmissible disease
- Prophylaxis and treatment not usually available. Examples include exotic haemorrhagic fever viruses.

Note: UTS *does not* currently have the facilities to contain Risk Group 4 microorganisms.

4. Directive principles

In the Responsible Conduct of Research Policy, the University has endorsed the principles of responsible research set out in the Australian Code for the Responsible Conduct of Research (the Code) and adopted them as a requirement for good research practice at UTS.

Further, the Code states that researchers must ‘maintain high standards of responsible research’ and ‘follow proper practices for safety and security’. This is also an expectation in conducting research at UTS.

5. Directive statements

5.1 General requirements for research that uses or engages with biological hazards and conditions of accreditation by the OGTR

UTS requirements for undertaking research involving interaction with biological hazards are outlined in this section.

UTS must comply with all conditions described in the OGTR's Guidelines for Accreditation of Organisations, including the establishment of an IBC and regular reporting to the OGTR.

Note: For research conducted outside of NSW, researchers must comply with the governing principles of this Directive, provided that such compliance does not breach relevant local legislation.

Research should not be conducted in other countries as a mechanism of avoiding compliance with this Directive and local legislation.

5.1.1 Establishment and management of the UTS IBC

The Vice-Chancellor's UTS IBC must be established in line with the requirements of the University's accreditation by the Regulator under section 92 of the Gene Technology Act. The UTS IBC composition and membership are outlined in the UTS IBC Terms of Reference (Word 51kb) (restricted access: UTS login only).

5.1.2 Reporting to OGTR

UTS must submit an annual report to the Regulator before 30 September each year and/or as requested by the OGTR. This report is composed by the Ethics Secretariat in collaboration with the UTS IBC Chair.

5.2 UTS IBC approval

All research and teaching activities involving the transport, intention to import, storage, use, interaction with and disposal of biological hazards require written approval by the UTS IBC prior to the work commencing. Researchers have personal responsibility for all matters relating to the safety of individuals interacting with biological hazards and compliance with the OGTR which is achieved by attaining UTS IBC approval.

Retrospective approval of the UTS IBC is not permitted, and any research involving transport, intention to import, storage, use, interaction with and disposal of biological hazards conducted without prior approval is considered a breach of this Directive and the Gene Technology Act.

5.2.1 Communication and monitoring

5.2.1.1 Communication to the UTS IBC

All communication to the UTS IBC must be made in writing to the Ethics Secretariat (restricted access: UTS login only). All applications need to be received by the Ethics Secretariat by each meeting's closing date. Any application not received by this date will be held over until the next UTS IBC meeting.

Further details about the UTS IBC application process can be found at Biosafety: forms and guidelines (restricted access: UTS login only).

5.2.1.2 Communication from the UTS IBC

Correspondence is sent from the UTS IBC to the Chief Investigator and nominated associate investigators by email from the Ethics Secretariat (on behalf of the UTS IBC). Researchers should not approach individual members of the IBC to discuss the

progress of pending applications. Copies of approval letters, including any conditions imposed, are also sent to the relevant Facilities Manager.

5.2.1.3 Official records of the UTS IBC

After each meeting, copies of the UTS IBC meeting minutes are circulated to the Vice-Chancellor, Deputy Vice-Chancellor (Research), and senior members of the Faculty of Science (Dean, Associate Dean of Research, Research Development manager). Minutes documents are confidential and access is made available only to aforementioned personnel, Ethics Secretariat and UTS IBC.

The UTS IBC annual report is submitted to the Deputy Vice-Chancellor (Research).

5.2.1.4 Monitoring of research

Following approval by the UTS IBC, the researcher, research, research group and/or relevant facilities under the approved application may be subjected to inspections by the UTS IBC at any time.

The UTS IBC may conduct unannounced inspections of any UTS facility that uses biological hazards. Announced inspections occur annually at a minimum, with a written report reviewed at the following UTS IBC meeting.

5.3 Managing biological hazards at UTS

This section outlines some of the expectations and responsibilities regarding management of various biological hazards while undertaking research at UTS. Many of the University's requirements are obligatory under either state or federal legislation.

5.3.1 Genetically modified organisms (GMO)

The Gene Technology Act regulates all dealings with GMOs. Both the Gene Technology Act and Regulations describe a number of classes of dealings with GMOs and corresponding approval processes and risk assessments. Every dealing with a GMO will need to be licensed by the Regulator unless it is identified as:

- an exempt dealing
- a notifiable low risk dealing (NLRD) or
- is listed on the Register of GMOs.

5.3.1.1 Exempt dealings are a category of GMO dealing that the Regulator has deemed to be, or has assessed over time as, posing a very low risk. Exempt dealings are described in Parts 1, 2 and Schedule 2 of the Regulations. The only legislative requirement for exempt dealings is that they must not involve an intentional release of a GMO into the environment. The OGTR's What are exempt dealings? provides more information and guidance.

5.3.1.2 Notifiable low risk dealings (NLRDs) are dealings with GMOs that have been assessed as possessing very low risk to the health and safety of people and the environment, providing certain risk management conditions are met. These conditions and the processes for the assessment of proposed NLRDs are outlined on the OGTR's What are notifiable low risk dealings?. The UTS IBC must prepare a record of assessment of each proposed NLRD and provide this record to the researcher(s) who requested the assessment.

5.3.1.3 The Register of GMOs is maintained by the Regulator, who may make a determination to include dealings with GMOs on the Register according to section 78 of the Gene Technology Act.

Prior to inclusion on the GMO Register, the dealings must first have been authorised by a GMO licence. Dealings will not be entered onto the GMO Register until the Regulator is satisfied that the risks posed by the dealings are minimal and that it is not necessary for anyone conducting the dealings to be covered by a licence in order to protect the health and safety of people or the environment. (See Part 6, Division 3 of the Gene Technology Act).

5.3.1.4 Licenced dealings are those dealings with GMOs that are not exempt or NLRDs. Licenced dealings will need to be licensed by the Regulator. A GMO licence is a legal instrument issued by the Regulator under the Gene Technology Act that sets down the conditions under which specified dealings with genetically modified organisms (GMOs) must be undertaken. These dealings can be either:

- DIRs — Dealings involving an Intentional Release of GMOs into the environment, or
- DNIRs — Dealings NOT involving an Intentional Release of GMOs into the environment.

The OGTR has all the official forms required for NLRD notifications, applications for licences, etc.

5.3.2 Pathogens

Microorganisms include bacteria, parasites, fungi or viruses. All work at UTS involving microorganisms which are identified as potential pathogens must utilise appropriate physical containment procedures corresponding to the degree of risk presented by the microorganism, as specified in 'Australia/New Zealand Standard: Safety in Laboratories, Part 3: Microbiology AS/NZS 2243.3' (see UTS: Safety and Wellbeing — Microbiological).

This Standard groups microorganisms into four risk groups based on the risk the microorganism could present to staff, the environment and the community, and describes the containment level required for each of these risk groups. If in doubt about the level of risk involved or the appropriate containment procedures required, contact the UTS: Safety and Wellbeing Branch.

Physical containment levels

PC1 is adequate if the organisms are not known to cause disease in healthy adults. Human blood, body fluids or other clinical specimens or tissues with a pathogen risk MUST NOT be handled in a PC1 laboratory.

A PC2 level is required for work involving moderate risk microorganisms associated with animal, plant or human disease. If the potential for aerosol production is high, primary containment equipment must be used (that is, a Class I or II biological safety cabinet).

A PC3 level applies to work involving infectious microorganisms that are likely to cause serious disease in plants, animals or humans or may present a risk if spread in the community. PC3 certification can ONLY be obtained via OGTR inspection.

All researchers at UTS who are dealing with pathogens or potential pathogens are expected to be aware of the risk levels and associated containment requirements, and to act accordingly.

5.3.3 Ionising radiation

All work at UTS using an ionising radiation source must comply with the requirements set down in the Radiation Control Act 1990 (NSW) and the Radiation Control Regulation 2013 (NSW).

In addition to the Radiation Control Act and Regulation, there are other documents that provide recommendations for minimum standards of radiation safety, for example, 'Australia/New Zealand Standard: Safety in Laboratories, Part 4: Ionizing Radiations AS/NZS 2243.4' (see UTS: Safety and Wellbeing — Radiation). These documents can be obtained from the Radiation Safety Officer or from the UTS Safety and Wellbeing Branch.

All research at UTS involving a radioactive substance, regardless of the activity level, is required to obtain UTS IBC approval.

5.3.4 Cytotoxic substances

The acquisition, use and disposal of cytotoxic substances at UTS must comply with relevant legislative requirements, applicable guidelines and established standards (see WorkCover's Cytotoxic Drugs and Related Waste Risk Management Guide (under review)).

WorkCover Authority NSW must also be notified if the substance you intend to use is listed as a prohibited or restricted carcinogen in Schedule 10 of the Work Health and Safety Regulation 2011 (NSW).

Approval from the UTS IBC is required to obtain for all research at UTS involving a carcinogen, whether or not it is listed in Schedule 10 of the Work Health and Safety Regulation.

5.3.5 Imported pathogens or GMOs

5.3.5.1 Import permits and quarantine approved premises

The Australian Quarantine and Inspection Service (AQIS) is part of the Australian Government's Department of Agriculture and Water Resources and is responsible for enforcing Australia's quarantine laws. The importation of some biological material is subject, under the Quarantine Act 1908 (Cwlth), to certain quarantine conditions outlined in the Biosecurity Import Conditions System (BICON).

Some products have been assessed as posing significant risk and are not allowed entry into Australia. Other products are only allowed into Australia upon the granting of an Import Permit from AQIS.

To determine the need to submit an Import Permit application, the import requirements for the proposed material should be checked on BICON. If the material is not on ICON, contact AQIS in the first instance for more information.

An Import Permit may be obtained by submitting an application to import quarantine material to AQIS (see Department of Agriculture and Water Resources: Import). AQIS will assess the application and may decide to grant an Import Permit subject to any conditions deemed necessary for safe importation, use and disposal of those products.

AQIS is also responsible for approving places where post-entry quarantine requirements may be carried out on a wide range of plant and animal products, to ensure that these activities are performed with a minimal degree of risk. These are referred to as approved arrangements (previously Quarantine Approved Premises (QAP)).

AQIS will determine, based on the Import Permit application whether the researcher needs to house the imported material (for example, pathogens or GMOs) in a QAP.

In any QAP, students and staff must be provided training to ensure continual adherence with the requirements of the QAP. The facility should also have laboratory procedures in place that meet the Australia/New Zealand Standard AS/NZS 2243.3, Safety in Laboratories — Part 3 Microbiology. Training should include these procedures.

5.3.5.2 Exposure of non-laboratory animals to an imported biological material

To manage the risks involved in the use of work involving the direct or indirect exposure of non-laboratory animals to imported biological material, a special or additional application for in vivo use of imported biological products must be completed. The Department of Agriculture and Water Resources provides guidelines for this type of activity.

Laboratory animals — including guinea pigs, hamsters, mice, rabbits, rats, rodents, and microorganisms — must be contained under laboratory conditions. Non-laboratory animals include chickens, sheep, cattle, etc.

5.4 Resolving breaches of the Directive

Breaches of this Directive should be resolved through the following processes and in accordance with the UTS Code of Conduct.

Concerns about use of biological hazards can be brought to the researcher or their supervisor, facility managers, the Research Ethics Manager, UTS IBC Chair or Deputy Chair or the Ethics Secretariat. If the concern is found to be the result of behaviour that is not in compliance with the decisions of the UTS IBC, then the UTS IBC will be notified.

5.4.1 Complaints and grievances

Complaints or concerns can originate from individuals or groups that are internal, or external UTS. Complaints may fall into the following categories:

- complaints from individuals who are not associated with the research (may include members of the public and visitors to the University)
- complaints by UTS staff or students
- disputes between researchers and the UTS IBC
- serious disagreements between members of the UTS IBC
- disagreements between the UTS IBC and UTS senior managers.

All staff have the right and responsibility to report incidents of incompetence, non-compliance or other breaches of this Directive directly to the UTS IBC.

5.4.2 General complaint principles

The following general principles guide the resolution of Directive breaches:

- The ultimate goal in considering any concerns or complaints is to ensure the safety of personnel associated with research involving biological hazards.
- All complaints must be treated confidentially and can be submitted anonymously if desired by the complainant.
- Any person who makes a complaint in good faith will not be disadvantaged.
- In the first instance, all enquiries, concerns and complaints can be directed to Research Ethics Manager. The complaint, with or without resolution, will be referred to the Director, Research and Innovation Office and the UTS IBC.

- All complaints will be taken seriously and resolved in a timely manner.
- All complaints, except those which are minor and do not involve breach of legislation, need to be reported to the Research Ethics Manager.
- Any member of the UTS IBC receiving a complaint is obliged to raise the matter with the Research Ethics Manager and/or UTS IBC Chair as soon as possible.
- UTS staff and students must be made aware of what complaint procedures exist.

5.4.3 Complaints management procedures

a. The Research Ethics Manager is authorised by the UTS IBC to monitor projects involving biological hazards to ensure they are proceeding in compliance with the relevant legislation and the decisions of the UTS IBC.
b. Concerns or complaints from internal and external stakeholders received via email, telephone or in a face-to-face conversation are recorded in writing by the Research Ethics Manager and kept in a separate file which only the Research Ethics Manager can access.
c. The Research Ethics Manager undertakes a preliminary investigation regarding the issues raised by the complainant.
d. The UTS IBC Chair is notified about the complaint and the results of the preliminary investigation and if necessary provides advice about the appropriate resolution of the concern or complaint.
e. The Chair and the UTS IBC should endorse the resolution of the complaint.
f. The complaint and its proposed or actual resolution are notified to the Director, Research and Innovation Office, the UTS IBC (at its next meeting) and the faculty's Associate Dean (Research).
g. The Research Ethics Manager informs the complainant of the outcome.

In exceptional cases, the UTS IBC Chair, Deputy Chair or Research Ethics Manager may place an immediate suspension on a project upon receipt of a complaint. The researcher is notified immediately if this occurs.

The UTS IBC may recommend to the Deputy Vice-Chancellor (Research) the withdrawal of a study if there is a major deviation from the UTS IBC-approved protocol or proven misconduct.

Where appropriate, or deemed necessary by the UTS IBC, the responsible researcher(s) may be subject to disciplinary action in relation to the complaint. In this instance, the matter will be referred to the relevant faculty's Associate Dean (Research) and Research Integrity Advisor.

All cases of serious non-compliance must be reported by UTS to the National Health and Medical Research Council (NHMRC) in the 'NHMRC annual statement of compliance' and may result in the withdrawal of research funding.

6. Roles and responsibilities

Accountable Officer	Implementation Officer	Researchers, supervisors	Research students
6.1 Compliance with conditions of accreditation			
Deputy Vice-Chancellor (Research)	**The Deputy Vice-Chancellor (Research)** is responsible for maintenance of the University's status as an accredited organisation under the Gene Technology Act and Gene Technology Regulations. **The Director, Research and Innovation Office and UTS IBC** will provide assistance in meeting the compliance requirements. **Deans, Associate Deans (Research) of faculties and Centre Directors** are responsible for: • promoting the awareness of policies, procedures and guidelines related to the ethical conduct of research involving use of biological hazards • training researchers and students in responsible and ethical research practice. **Director, Research and Innovation Office** is responsible for: • providing advice on implementing and administrating the Directive • managing the processes through which a research project gains approval to be conducted, including the approval from UTS IBC • ensuring UTS IBC is appropriately constituted • facilitating access to information about the ethical conduct of research and the procedures for seeking approval and reporting on the completion of research.	**All researchers** are responsible for ensuring that their conduct of research complies with the statements in this Directive as well as with state and federal legislation. **Research supervisors** are responsible for ensuring that research students are aware of the requirements of the research they will be conducting and have complied with the requirements of the particular committee.	**Research students** are responsible for ensuring that their conduct of research complies with the statements in this Directive as well as with state and federal legislation. Research students should be aware of the requirements of the research they will be conducting and have complied with the requirements of the UTS IBC.

6.2 Biosafety approval			
Deputy Vice-Chancellor (Research)	**UTS IBC** is responsible for: • proposing amendments to the Directive, and • providing comments and feedback in the consultation process when the Directive is due for review. **Ethics Secretariat** is the primary point of contact for: • establishing and maintaining the official file of the Directive • proposing amendments as required, and • managing the consultation process when the Directive is due for review.	**All researchers and supervisors** are responsible for: • seeking ethics approval when required and for keeping clear and accurate records of the research process, including methodologies and data sources and any approvals granted. • ensuring that the design and conduct of their research complies with the University's policies, directives and guidelines on ethical conduct and the responsible conduct of research.	**Research students** are responsible for: • actively engaging with the research training opportunities offered through the Graduate Research School and their faculty/research strength • seeking guidance from their supervisor on the ethical conduct of their research • ensuring that the design and conduct of their research complies with the University's policies, directives and guidelines on ethical conduct and the responsible conduct of research.
6.3 Biological hazards			
Deputy Vice-Chancellor (Research)	**Research Ethics Manager** and the **Ethics Secretariat** are responsible for: • communicating the decisions of the UTS IBC to the researchers and senior management • promoting the awareness of policies, procedures and guidelines related to the ethical conduct of research involving biological hazards.	**Researchers** and **supervisors of research students** are responsible for: • responding to the UTS IBC comments in a timely matter to enable finalisation of the biosafety approval • identifying and providing appropriate supervision and training for research students.	

6.4 **Resolving** breaches of the Directive			
Deputy Vice-Chancellor (Research)	**Director, Research and Innovation** is responsible for: • ensuring that processes outlined in this Directive and in UTS Responsible Conduct of Research Policy are implemented. **The Designated Person** in research integrity under the Code (Deputy Vice-Chancellor (Research)) is responsible for: • ensuring that processes outlined in this Directive and in UTS Responsible Conduct of Research Policy are implemented.	**Researchers** are responsible for: • being aware and complying with this Directive and • relevant University policies and agreements.	**Research students** are responsible for: • being aware and complying with this Directive and • relevant University policies and agreements.

7. Acknowledgements

Department of Agriculture and Water Resources import website

Office of the Gene Technology Regulator

OGTR Guidelines for the Accreditation of Organisations

UTS Biosafety Application Guidelines – Research and Teaching (Word 2.1mb)
(restricted access: UTS login only)

8. Version control and change history

Effective date	Version	Approved by, resolution no. (date)	Amendment
20/03/2014	1	Vice-Chancellor (20/02/2014)	New Directive
19/08/2016	1.1	Council, COU/14-5/106 (15/10/2014)	Consequential changes to align with changes to the Student Rules.