

**PROJECT INVOLVING BIOLOGICAL MATERIAL ASSESSMENT REQUIREMENTS**

 **Research and Innovation Services**

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| **Name of Assessor** |  |
| **Date of Assessment** |  |
| **Title of Protocol** |  |
| **Facilities to Be Used** |  |

**BACKGROUND**

Often the most significant risk of loss or injury does not occur during the project but during the initial assessment of project risks and risk mitigation strategies. Misclassifying risk as being negligible, exempt or not requiring regulatory approvals can unwittingly lead to damaging the health and safety of people, animals and the environment, breaching State, Federal or International law, and damaging the reputation of the University.

The University is keen to support you to identify, assess, minimise and manage risk. This document will help guide you to sources of support and project approvals that may be required: to help you keep, yourself, your staff, students and your community safe.

IF UNSURE OF ANY ITEMS

You are more than welcome to contact the

Biosafety Officer biosafety@unisa.edu.au,

Animal Ethics Officer animalethics@unisa.edu.au,

Human Ethics Officer humanethics@unisa.edu.au,

Research Integrity Manager researchintegrity@unisa.edu.au,

Chemical Safety Officer chemsafety@unisa.edu.au, or

Radiation Safety Officer hsim.safetywellbeing@unisa.edu.au.



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| **Project Protocol****Briefly list in point form, the project steps.** |
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**PROJECT RISKS**

Do you intend to undertake teaching or research involving the use of biological material which solely consists of:

[ ]  Purified or synthesised inert DNA, RNA or protein, and which is not being used for gene technology.

[ ]  Substances disinfected, neutralised or inactivated, or dried on absorbent material, or substances fit for human consumption, and not infectious or contaminated with a toxin or pathogen, nor being used for gene technology

[ ] Cell lines that have not been genetically modified **and** the supplier can confirm that these cell lines do not contain infectious agents and has classified their risk as either BSL1, RG1 or PC1

[ ] Microorganisms that have not been genetically modified **and** are risk group level is either BSL1, RG1 or PC1.

[*Appendix 1*](#Appendix1) *contains the definition of organisms that are not gene technology.*

[ABSA Risk Group Database](https://my.absa.org/riskgroups) *lists risk levels of microorganisms.*

If any of the above were selected, an IBC application is not required.

If uncertain contact biosafety@unisa.edu.au.

Other approvals may be necessary, such as Human Research Ethics Committee, Animal Ethics Committee, Chemical Advisory Safety Committee or Radiation Safety Committee.

Do you intend to undertake teaching or research involving the use of:

[ ] Cell Lines assessed as BSL2, RG2, PC2 or the infectious status of the material is unknown, and not genetically modified

*Hint: Check the Technical Data Sheet provided by the commercial cell line company for:*

1. *Risk classification of the cell line*
2. *If the cell line is infected with a virus or parasite*
3. *If the cell line has been genetically modified*

[ ] [Risk Group 2](https://my.absa.org/riskgroups) or higher organisms

[ ]  Human tissue or fluids

[ ] Untreated biological material

[ ] Feral, native, undomesticated, or diseased animal

[ ] Animal, Plant or Organisms that could transmit harmful toxins

[ ] Untreated biological material which does not fit into the above four categories

[*Appendix 2*](#Appendix2) *contains a definition of biological material*)

If any of the above were selected, a [Biological Hazard Application form](https://i.unisa.edu.au/siteassets/staff/ris/docs/biosafety/ibc-4.3_biological_hazard_appl_form.docx) must be submitted to the Institutional Biosafety Committee: biosafety@unisa.edu.au and attach a copy of this completed form.

Do you intend to undertake teaching or research involving the use of:

[ ] Genetically Modified Organisms or gene technology

*Genetically modified organisms include, among other things, cell lines that have been previously genetically modified.* [*Appendix 2*](#Appendix2) *contains the definition of what is not gene technology nor a Genetically Modified Organism.*

**If the above was selected, a** [GMO Application form](https://i.unisa.edu.au/siteassets/staff/ris/docs/biosafety/ibc-2.7_gmo_appl_form.docx) **must be selected to the Institutional Biosafety Committee:** biosafety@unisa.edu.au

Do you intend to:

[ ]  import or export animals (including invertebrates), plants, soils or other materials into or out of Australia

**If the above was selected, please refer to the** [UniSA Biosecurity webpage](https://i.unisa.edu.au/staff/research/biosafety-and-permits/quarantine-and-transfer-of-goods/)

Do you intend to undertake teaching or research involving the use of:

[ ] material or technology that has actual or potential applications for [biological weaponry](https://i.unisa.edu.au/staff/research/biosafety-and-permits/defence-export-controls/)

[ ] genetic modification of human embryos

*Note: This category includes amongst other things, mitochondrial donation.*

[ ] [Security Sensitive Biological Agents](http://www.health.gov.au/SSBA#standards)

[ ] Biological material provided from, or exported to, individuals or countries specified under [Sanction Controls](https://i.unisa.edu.au/staff/research/biosafety-and-permits/sanctions/)

**If any of the above were selected, the Head of your Academic Unit and the Manager: Research Integrity:** ResearchIntegrity@unisa.edu.au **must be contacted.**

**OTHER APPROVALS**

[ ]  Does the work involve using whole animals or animal fluids or tissues for which prior ethics approval has not been obtained?

*Note: Processed tissues (such as tissue set in blocks, fixed or onto slides) do not require AEC notification.*

**If the above was selected**, **and if UniSA Animal Ethics Committee (AEC) approval has not already been granted, please refer to the** [Animal Ethics webpage](http://i.unisa.edu.au/staff/research/research-ethics/animal-ethics/), **to submit an application for AEC approval.**

[ ]  Does the work involve the collection or use of blood or semen, either **your own** or from **someone else**?

*Note: processed tissues (such as tissue set in blocks, fixed, onto slides or established tissue culture cell lines) do not require HREC notification.*

[ ]  Does the work involve the collection or use of saliva, urine, faeces, sweat or tears collected from people **other than yourself**?

*Note: processed tissues (such as tissue set in blocks, fixed, onto slides or established tissue culture cell lines) do not require HREC notification.*

[ ]  Does the work involve human participants, embryos or data (including medical history)?

**If any of the above were selected,** **and if UniSA Human Research Ethics Committee approval has not already been granted, please refer to the** [Human Research Ethics webpage](https://i.unisa.edu.au/staff/research/research-ethics/human-research-ethics/), **to submit an application for HREC approval.**

[ ]  Does the work involve radiation?

**If the above was selected, and an approval to use radiation has not already been granted, please refer to the** [Radiation Safety webpage](https://i.unisa.edu.au/staff/ptc/safety-and-wellbeing/consultation/radiation-safety-committee/) **or your Radiation Safety Officer (RSO). Contact your departmental RSO for information. Applications for radiation approval can be submitted to the RSO using the following form:** [ResearchProposal Requiring Radiation Approval (WHS 22)](https://i.unisa.edu.au/staff/ptc/resources/whs-resources/whs-forms/).

[ ]  Does the work involve highly toxic, hazardous, carcinogenic/teratogenic or cytotoxic chemicals or drugs?

**If the above was selected, please refer to the** [Chemical Hazard Approvals webpage](https://i.unisa.edu.au/staff/ptc/safety-and-wellbeing/hazards-and-risks/inherent-hazard-types/chemicals-and-nanomaterials/).

[ ]  Does the work have actual or potential commercial applications?

**If the above was selected, contact** [UniSA Ventures](http://www.unisa.edu.au/ventures/?_ga=2.217870229.280173456.1533511326-1944250662.1448326492) **for any assistance.**

[ ]  Does the work have actual or potential military applications, including use as a biological weapon?

**If the above was selected, and a permit has not been granted or you are not sure about the defence implications of the activity, please refer to the** [Defence Export Controls](https://i.unisa.edu.au/staff/research/biosafety-and-permits/defence-export-controls/) **webpage.**

[ ]  Does the work involve the import or export of animals (including invertebrates), plants, soils or other materials into or out of Australia?

**If the above was selected, refer to** [Biosecurity webpage](https://i.unisa.edu.au/staff/research/biosafety-and-permits/quarantine-and-transfer-of-goods/).

[ ]  Does the work involve using a genetically modified organism in the course of the manufacture of a thing that is not the GMO?

**AND**

The thing is subject to regulation by other agencies such as Food Standards Australia, Australian pesticides and Veterinary Medicines Association, Therapeutic Goods Administration, Department of Agriculture and Water Resources or Department of Defence?

*Note: a thing includes amongst other things synthetic biology, electronic forms or magnetic forms.*

**If the above was selected,** **apply to the appropriate agency for a permit.**

**For further information, contact the Biosafety Officer,** biosafety@unisa.edu.au.

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| **Declarations** |
| **Project Supervisor Declaration** |
| I am aware of my responsibilities to ensure that any person conducting this work is appropriately trained and knowledgeable of and following the relevant guidelines and regulations. |
| I have considered the potential risks that conducting this project could pose to people, animals and the environment. And I will implement appropriate actions and precautions to minimise these risks.  |
| Where the biological material is received from sources outside the institution responsible for the project, I will confirm its identity. |
| In the event I become aware of an unintentional release, accident or another incident of occupational or environmental exposure to potentially hazardous biological material, I will ensure that actions are taken to minimise harm. Furthermore, I will inform the Institutional Biosafety Committee and People, Talent and Culture as soon as practicable of any incidents, accidents or unintentional releases. |
| I will not encourage nor overlook unsafe or unethical work practices.  |
| I am aware that breaches of the legislation are serious matters and that penalties could include loss of OGTR Accreditation status for the organisation, imprisonment and/or substantial fines. |
| If I become aware of an emerging Public Health Emergency or Biosecurity Incident which might increase the biosafety risks of this project, I will contact the Biosafety Officer or IBC to review this project’s risk mitigation strategies.  |
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Principal Investigator/Supervisor Name Signature Date

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| **Operations/General/Facility Manager Declaration** |
| I have reviewed this completed form and considered the potential risks of this project to people, animals and the environment. |
| I will not encourage nor overlook unsafe or unethical work practices. |
| I will ensure that appropriate resources, reporting and auditing systems are established and maintained, to minimise and adequately control the risks of this project as outlined in this form. |
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Operations/General/Facility Manager Name Signature Date

Keep a copy Of The Completed form for your records

Note that the IBC or People, Talent and Culture may ask to see this form, and other risk assessments of this project.



**Appendix 1**

Gene technology is a set of techniques used to artificially manipulate, modify, or recombine DNA or

other nucleic acid molecules to modify an organism or population of organisms.

**Techniques That Are Not Gene Technology**

 As per Gene Technology Regulations 2001, effective 8 October 2020

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| **Item** | **Description of technique** |
| 1 | Somatic cell nuclear transfer (SCNT), if the transfer does not involve genetically modified material. |
| 2 | Electromagnetic radiation-induced mutagenesis. |
| 3 | Particle radiation-induced mutagenesis. |
| 4 | Chemically-induced mutagenesis. |
| 5 | Fusion of animal cells, or human cells, if the fused cells are unable to form a viable whole animal or human. |
| 6 | Protoplast fusion, including fusion of plant protoplasts. |
| 7 | Embryo rescue. |
| 8 | In vitro fertilisation (IVF). |
| 9 | Zygote implantation. |
| 10 | A natural process, if the process does not involve genetically modified material.Examples of natural processes include conjugation, transduction, transformation and transposon mutagenesis. |
| 11 | Introduction of RNA into an organism, if:(a) the RNA cannot be translated into a polypeptide; and(b) the introduction of the RNA cannot result in an alteration of the organism’s genome sequence; and(c) the introduction of the RNA cannot give rise to an infectious agent. |

Changes to methylation of genomic deoxyribonucleic acid (DNA) by RNA introduction are not considered an alteration of an organism’s genome sequence.



**Organisms That Are Not Genetically Modified Organisms**

As per Gene Technology Regulations 2001, effective 8 October 2020

An organism is not a genetically modified organism if:

(a) one or more items in Schedule 1 applies to the organism; and

(b) the organism has not been modified by gene technology except for any modifications described in those items; and

(c) the organism has not inherited any traits from an organism (the initial organism), being traits that occurred in the initial organism because of gene technology, except as described in item 9 in Schedule 1 (see below); and

(d) none of the items in Schedule 1B applies to the organism.

This means: The organism has neither had its genome modified by oligonucleotide‑directed mutagenesis; nor

been modified by repair of single-strand or double-strand breaks of genomic DNA induced by a site-directed nuclease, if a nucleic acid template was added to guide homology-directed repair.

**Schedule 1**

Gene Technology Regulations 2001, effective 8 October 2020

| Item | Description of organism |
| --- | --- |
| 1 | A mutant organism in which the mutational event did not involve the introduction of any foreign nucleic acid (that is, non‑homologous DNA, usually from another species). |
| 2 | A whole animal, or a human being, modified by the introduction of naked recombinant nucleic acid (such as a DNA vaccine) into its somatic cells, if the introduced nucleic acid is incapable of giving rise to infectious agents. |
| 3 | Naked plasmid DNA that is incapable of giving rise to infectious agents when introduced into a host cell.  |
| 6 | An organism that results from an exchange of DNA if:(a) the donor species is also the host species; and(b) the vector DNA does not contain any heterologous DNA. |
| 7 | An organism that results from an exchange of DNA between the donor species and the host species if:(a) such exchange can occur by naturally occurring processes; and(b) the donor species and the host species are micro‑organisms that:(i) satisfy the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 1; and(ii) are known to exchange nucleic acid by a natural physiological process; and(c) the vector used in the exchange does not contain heterologous DNA from any organism other than an organism that is involved in the exchange. |
| 8 | An organism that is descended from a genetically modified organism (the ***initial organism***), if none of the traits it has inherited from the initial organism are traits that occurred in the initial organism because of gene technology.  |

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| **Item** | **Description of organism** |
| 9 | 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, if: (a) the initial organism was not a genetically modified organism (because of the application of regulation 5); or (b) all such inherited traits are traits that occurred in the initial organism as a result of a modification described in an item in this Schedule.  |
| 10 | An organism that was modified by gene technology but in which the modification, and any traits that occurred because of gene technology, are no longer present.  |
| 11 | *Agrobacterium radiobacter* strain K1026.  |
| 12 | *Pasteurella multocida* strain PMP1.  |

NOTE: Organisms which are NOT GMOs, as per item 1, include organisms in which:

1. No nucleic acid template was added to the cell to guide genome repair, following site-directed nuclease application (e.g. CRISPR/Cas9, zinc finger nucleases, meganucleases and TALENs, without repair guide)

And

1. No other traits from gene technology are expressed (e.g. cas9 transgene, expressed site-directed nuclease)

**Appendix 2**

# **Definition of Biologically Hazardous Material**

Biological material is defined as organic substances. Not all biological material is hazardous to humans, animals, plants or the environment.

Biologically Hazardous Material is defined by Comcare https://www.comcare.gov.au/safe-healthy-work/prevent-harm/biological-hazards as organic substances that present a threat to the health of people and other living organisms.

Biologically hazardous material can be categorised into seven broad groups. Biologically hazardous material includes, amongst other things:

1. Human body matter that may contain viral or bacterial disease: blood, tissues, vomit, urine, faeces, saliva, breast milk, semen, lung aspirates, skin etc.
2. Microorganisms that are pathogenic, allergenic, toxic or pests including viruses, zoonoses, bacteria, prions, spores, fungi, moulds, yeast, algae, etc., including those that have been genetically modified.
3. Living animals including cattle, sheep, poultry, aquatic animals, invertebrates, wild animals, and their urine, faeces, etc., reproductively active eggs, larvae, etc., including those that have been genetically modified.
4. Animal products including raw and cooked meat not fit for human consumption, body fluids and material, milk and eggs etc.
5. Laboratory cultures including pathogenic, allergenic, toxic or pest animal and human tissue, bacterial, viral, cellular, both genetically modified or wild type cultures, etc.
6. Environmental material including pest plants, soil, plants which may contain pathogens or act as allergens, organic dusts, rubbish, unaged compost, wastewater, sewerage, food which is not fit for human consumption etc.
7. Genetic material which produces pathogenic, allergenic, toxic or pests which are biologically active substances or organisms.

**Definition of microorganism:**

Microorganism includes any of the following (whether naturally occurring or synthetically created):

 (a) single celled organism (whether an animal or plant);

 (b) bacterium;

 (c) protozoan;

 (d) fungus;

 (e) plant pathogen;

(f) virus;

(g) zoonoses;

(h) prions;

(i) spores;

(j) moulds;

(k) yeast;

(l) aglae

**Appendix 3**

**Risk Assessment Resources**

Research and Innovation Services (RIS) [Checklist for Projects Involving Biological Material](https://i.unisa.edu.au/siteassets/staff/ris/docs/biosafety/projects_involving_biological_material.docx)

ABSA [Risk Grouping of microorganisms](https://my.absa.org/riskgroups)

RIS [Biosafety webpage](https://i.unisa.edu.au/staff/research/biosafety-and-permits/biosafety/)

RIS [Gene Technology webpage](https://i.unisa.edu.au/staff/research/biosafety-and-permits/gene-technology/)

RIS [Biosecurity webpage](https://i.unisa.edu.au/staff/research/biosafety-and-permits/quarantine-and-transfer-of-goods/)

[Security Sensitive Biological Agents](http://www.health.gov.au/SSBA#standards) list

RIS [Defence Export Controls](https://i.unisa.edu.au/staff/research/biosafety-and-permits/defence-export-controls/) (biological weapons) webpage