Research Ethics and Institutional Biosafety Procedure

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Purpose

The purpose of the Research Ethics and Institutional Biosafety Procedure is to guide researchers (including students undertaking research) and teaching staff of Federation University and Federation Training through the Animal Ethics, Human Ethics and Institutional Biosafety application process.

This procedure will assist researchers, including students, and teaching staff where applicable, to meet their responsibilities to conduct ethical research involving live animals or humans, teaching programs involving live animals, and/or work with genetically modified organisms (GMOs), in accordance with current Commonwealth, State and Territory legislation and other guidelines.

Scope

This procedure applies to:

- All staff, including sessional staff, employed by the University, Federation Training, or any controlled entity;
- All persons, including Adjunct and Honorary staff, engaged in research under the auspices of the University, Federation Training, or any controlled entity;
- All students of the University who engage in research and/or research related activities, related to their studies, while enrolled at the University.

Any teaching courses or research projects at Federation University or Federation Training that involve live animals must not commence without prior written approval from the Federation University Animal Ethics Committee.

Any research project Federation University or Federation Training that involve collection and/or analysis of human data must not commence without prior written approval from the Federation University Human Research Ethics Committee.

Any teaching programs or research projects at Federation University or Federation Training that involve Genetically Modified Organisms must not commence without prior written approval from the Federation University Institutional Biosafety Committee.

Legislative Context

- Gene Technology Act 2000
- Gene Technology Regulations 2001
- National Health and Medical Research Council Act
- Other Australian Legislation (by State)
- Prevention of Cruelty to Animals Act 1986

National and State Codes and Guidelines

- AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research
- Australian Code for the Care and Use of Animals for Scientific purposes8th Edition, 2013 (pdf, 450kb)
- Australian Code for the Responsible Conduct of Research
- Australian Code for the Responsible Conduct of Research (pdf,230kb)
- Guidelines for Animal Ethics Committees in Victoria
- Guidelines for the care and use of Australian native mammals in Research & Teaching
- Guidelines to promote the well-being of animals used for scientific purposes
- National Statement on Ethical Conduct in Human Research (2007), Updated 2023
- NSW Department of Primary Industries – Guidelines in wildlife research
- Victorian Codes of Practice for Animal Welfare

Definitions

Term	Definition
Amendment / Amendment Request	Any proposed change or variation to an approved project must be submitted to the relevant compliance committee (AEC, IBC or HREC) for assessment and approval prior to implementation of the change. This includes any amendment to activity including:

	• Technique, procedure, location, change in number of animals involved etc. • Change to personnel, or Principal researcher. • Extension to the approved research period (max one year extension to animal research projects).
Animal Ethics Committee (AEC)	A University Committee established in accordance with the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes 8th edition, to oversee and approve animal use in research.
Application	A request for approval from an Animal Ethics Committee (AEC), Institutional Biosafety Committee (IBC) or Human Research Ethics Committee (HREC) to carry out a research project or teaching activity.
Approval Withheld	A review outcome used in relation to a project application which requires that ethical issues be satisfactorily addressed and the application resubmitted to the relevant Committee before the project can commence.
Approved	A review outcome that grants approval for a project to commence.
Approved with comment	A review outcome that grants approval for a project to commence, but with comment from the relevant Committee.
ARC	Australian Research Council.
Australian Code for the Care and Use of Animals for Scientific Purposes 8th Edition (2013)	Provides guidelines for the ethical use of animals in research and teaching, and outlines the requirements for the function of an institutional Animal Ethics Committee. Generally referred to as 'the Code'.
Chief Investigator	The lead researcher on a project application for approval. This person must be a member of staff, and will hold responsibility for the project. Honorary and adjunct members may not be listed as Chief Investigator. May also be referred to as Principal Researcher.
Co-Investigator	Person/s other than the Chief Investigator who make/s a significant contribution to the planning, design implementation or outputs of a research projects, including collection, analysis or interpretation of data. Also referred to as Co-Researcher.
Compliance	Acting in accordance with the relevant Code, National Statement and/or Regulation, and Conditions of Approval as listed on the Outcome Notification.
Conditions of Approval	Conditions outlined in approval notices must be adhered to, in order to ensure continued project approval.
DIR	Dealing involving intentional release – A category of dealings with GMOs that take place outside of containment facilities and involve an intentional release of GMOs into the Australian environment.
DNIR	Dealing not involving intentional release - A category of dealings with GMOs that take place in contained facilities, do not involve an intentional release of GMOs into the Australian environment, and do not meet the criteria for classification as Exempt Dealings or Notifiable Low Risk Dealings.

ED	Exempt dealing - 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.
EDD	An Emergency Dealing Determination (EDD) is a legislative instrument made under the Gene Technology Act 2000. The emergency provisions in sections 72A - 72E of the Act give the responsible Minister the power to expedite an approval of dealings with a GMO in an emergency.
Executive Committee	An executive of the AEC, formed according to requirements of The Code to approve minor amendments and other matters not requiring full Committee attendance.
Gene Technology Act	The nationally consistent legislative scheme for gene technology is comprised of the Commonwealth Gene Technology Act 2000 and Gene Technology Regulations 2001, and corresponding State and Territory legislation. Generally referred to as 'the Act'.
GM	Genetically Modified
GMO	Genetically Modified Organisms. In Australia, all dealings with live and viable genetically modified organisms (GMOs), including import, are illegal unless authorised under the Gene Technology Act.
GMO Register	The Gene Technology Regulator may make a determination to include dealings with GMOs on the GMO Register. To be included 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.
Governing Body	The Governing body refers to the National Health and Medical Research Council/ Australian Research Council.
Human Participant	Research participants who are personally interacting with the investigator, subject to observation, and/or those whose records are being accessed. Also referred to as participants.
Human Research Ethics Committee HREC	A University Committee established in accordance with the National Health and Medical Research Council requirements to oversee and approve research involving humans or human data.
Institutional Biosafety Committee (IBC)	Institutional Biosafety Committee, a Federation University committee established in accordance with the Office of Gene Technology Regulator OGTR for the purpose of assessing any research project involving genetically modified material.
Incident/Adverse/Unexpected event	Any outcome that may have a negative impact on a participant, the welfare of animals, or the researcher, and was not foreseen in the approved project. It is one of the standard conditions of approval that any adverse unexpected incident be formally reported to the relevant compliance committee.

Low Risk	A category of risk determined according to the National Statement definitions of risk, that would permit an application to be reviewed by the Low Risk Human Research Ethics Committee, a sub-committee of the HREC.
Low Risk Human Research Ethics Committee	A sub-committee of the University Human Research Ethics Committee. This Committee assesses and approves low risk human research applications in accordance with the National Statement.
Monitoring	The process of verifying that the conduct of research conforms to the approved proposal.
National Statement	National Statement on Ethical Conduct in Human Research. All researchers and teachers named on any human research ethics application, should be familiar with this document.
NGO	Non-Government Organisation
NHMRC	National Health and Medical Research Council, Australia's leading expert body promoting the development and maintenance of public and individual health standards.
NLRD	Notifiable Low Risk Dealings (NLRDs) are activities with GMOs undertaken in containment (ie: not released into the environment) that have been assessed as posing low risk to the health and safety of people and the environment provided certain risk management conditions are met.
Non-Compliance	Failure or refusal by researcher/s to act in accordance with the Standard Conditions of Approval for their project, respond to the directions of the relevant compliance committee, or be in breach of the relevant guide or legislation.
Not Approved	A review outcome for a project that has not been given Committee approval to commence.
OGTR	Office of the Gene Technology Regulator - National Regulatory Scheme for Genetically Modified Organisms has the specific responsibility to protect the health and safety of people, and to protect the environment, by identifying risk posed by or as a result of gene technology.
PC1	Physical Containment Level 1
PC2	Physical Containment Level 2
Principal Researcher	The lead researcher (or lead member of the teaching staff) on a project application for approval. This person must be a member of staff, and will hold responsibility for the project. Honorary and adjunct members may not be listed as Principal Researcher. May also be referred to as Chief Investigator.
Provisional Approval	A review outcome for a project approved subject to particular issues being satisfactorily addressed as directed by the relevant Committee. The project must not commence until final approval is granted.

Quorum	The minimum number of Committee members required at any meeting to make the proceedings of that meeting valid in accordance with the Terms of Reference.
RARMP	Risk Assessment and Risk Management Plan
Risk	The function of the magnitude of harm and the probability that it will occur.
Risk Assessment	The National Statement defines project risk level as either negligible, low or above low risk. The risk level determines the application review pathway.
Special Conditions	These conditions apply in relation to suspended projects, or to projects where approval has been withdrawn. Where approval has been withdrawn, a researcher must not continue the research, and must comply with any special conditions required by the relevant compliance Committee.
Standard Conditions of Approval	Standard conditions outlined in the relevant guides/legislation which must be adhered to, in order to ensure continued approval for projects involving animal or human data or genetically modified organisms. These are listed on the Approval notification for easy reference.
Terms of Reference	Terms of Reference show how the scope of the Committees will be defined, developed, and verified. Generally referred to as ToR.
The Act	The Prevention of Cruelty to Animals Act 1986, referred to as 'the Act' is legislation that consists of the principal Act, principal Regulations and a large number of Codes of Practice.
The Act	The Gene Technology Act 2000 referred to as the act is the nationally consistent legislative scheme for gene technology, and is comprised of the Commonwealth *Gene Technology Act 2000* and Gene Technology Regulations 2001, and corresponding State and Territory legislation.
The Code	The Australian Code for the Responsible Conduct of Research.
The Code	Australian Code for the Care and Use of Animals for Scientific Purposes 2013, referred to as 'the Code', is a mandatory Code protecting the welfare of animals, and is legislated by the Prevention of Cruelty to Animals Act, 1986. All researchers and teachers named on any animal ethics application, must be familiar with this document.
Variation (to a project)	Any proposed amendment or modifications researchers might wish to make to an approved project. All variations/amendment requests require assessment and approval from the relevant compliance committee prior to implementation of the change. They may include: • Technique, procedure, location, change in number of animals or human participants, involved etc. • Change to research personnel • Extension to the approved research period (max one year extension to animal research projects).

Actions

In accordance with relevant guides and legislation (including the Australian Code for the Care and Use of Animals for Scientific Purposes, National Statement on Ethical Conduct in Human Research), all research or teaching activities involving care and use of animals, research involving genetically modified organisms other than are not exempt dealings (see below), and all research activities involving human data must:

- Be subject to ethical review, approval and monitoring by the relevant compliance committee (AEC, IBC or HREC);
- Commence only after approval has been granted by the relevant committee;
- Be conducted in accordance with the committee approval;
- Cease if approval from the relevant committee has expired, is suspended or is withdrawn.

For Exempt Dealings involving genetically modified organisms, please see the relevant section of this procedure under the heading ‘Institutional Biosafety,’ below.

All those involved in any project subject to review by the AEC, IBC or HREC must be aware of the relevant Commonwealth, State and Territory legislation and guidelines, relevant guidelines and legislation in the jurisdictions in which the project is conducted, as well as relevant Federation University policies and procedures.

The following sections of this procedure outline processes related to each of the three compliance committees, as indicated.

Application for New Project Processes

Animal Ethics Committee Approval

Researchers and teaching staff using animals in research or teaching activity must demonstrate familiarity with the latest version of the *Australian code for the care and use of animals for scientific purposes* and its application to their project.

Researchers must review submission deadlines and meeting dates available on the Federation University Research Ethics website to determine the most appropriate submission date for their application.

Researchers should complete the following steps to gain AEC approval any work involving the care and use of animals.

	ACTIVITY	RESPONSIBILITY	STEPS
1.	Download and complete an Animal Ethics application form. The form can be found on the Research Ethics website.	Principal Researcher Research Team	Read the information provided on the application form, and be familiar with areas of the Code relevant to your project. Be familiar with any relevant Standard Operating Procedures (listed on the AEC website) and make reference to these within the application. In the case of an application for a student research project, the

			Principal Supervisor must sign off as the Principal Researcher. The Principal Researcher must maintain responsibility for the project. Supervisors must mentor research students throughout the development of their animal ethics application and provide guidance throughout the application process. The Research Services Ethics Office can be consulted in regard to administrative aspects of an application. Ensure the application form is fully completed and signed by the entire Research Team. *Note*: If any Genetically Modified Organisms (GMOs) will be involved in the project, the researcher/s must also submit an application for review by the Institutional Biosafety Committee (IBC), see below.
2.	Attach supplementary documentation	Principal Researcher Research Team	Attach copies of any required supplementary information. Examples of documentation that may be required: • Evidence of approval from external agencies (*note*: Some external agencies will only grant approval after AEC approval is obtained. In this instance, the AEC will list this as a condition of approval, and evidence of this approval must be submitted to the AEC before the project commences). • Evidence of training undertaken by researchers in order to competently undertake required procedures. • Monitoring sheets/daily check form, for animals held in care. These should cover all observations regarding food, water, breathing, signs of

			dehydration, abnormal activity, surgery, recovery, posture etc.
3.	Obtain approval from relevant Institute/Centre/other authority	Principal Researcher Research Team	Applications must be signed by the: • Principal Researcher, and • All co-Researchers Applications should then be reviewed, and approved for submission to the AEC by one of the authorised personnel listed on the form and/or Federation University Research Ethics website. *Note:* In the case of an application for a student research project, the Principal Supervisor must sign off as the Principal Investigator and, as Principal Investigator, is responsible for the project conduct.
4.	Submit the application for informal review (optional)	Principal Researcher Research Team	Should they wish to, researchers are able to submit the application to Research Services at least two weeks prior to the due date (as advertised on the AEC website), and request informal review and feedback from the AEC. The AEC will endeavour to provide the applicant with early feedback to expedite potential approval of the application, but whether such feedback can be practically provided depends on the workload of the AEC. Any changes recommended in the feedback from the AEC must then be made, and the amended application must be submitted to Research Services by the due date for the next meeting. *Note:* This earlier review and feedback does not constitute approval or otherwise by the AEC.
5.	Submit the application to the AEC for formal review	Principal Researcher Research Team	Submit completed and fully authorised copy of the application, plus all attachments, (in word.doc format or pdf format) as per the

			submission method and deadlines detailed on the Research Ethics website for presentation at the relevant AEC meeting. • Ensure application has been reviewed and includes all required signatures. • Submit the completed application, including all attachments, to the Ethics Office as per the submission method detailed on the Research Ethics website. Researchers are responsible for follow-up with an email or phone call prior to the Agenda Due Date to obtain the Project Number & Meeting Number if they have not otherwise been advised by the Ethics office that the application has been accepted. *Note:* Ensure the application and all attachments are submitted to the Ethics Office by the due date and time. Late submissions will be carried over until the following AEC meeting.
6.	Outcome notification	Ethics Office	The Ethics Office will contact the Principal Investigator advising of the outcome of the meeting. *Note*: projects must not commence until full approval has been received.

Requesting Urgent AEC Review

Researchers should complete the following steps to request acceptance of an application for urgent review.

	ACTIVITY	**RESPONSIBILITY**	**STEPS**
1.	Submit request for urgent review	Principal Researcher Research Team	Review of an ethics application with an urgent deadline is possible at times, but will only be considered under **exceptional** circumstances. A case justifying such a measure is required.

			Requests for urgent review should be directed to the Research Services Ethics Team. The AEC Chair will determine if the application will be accepted for urgent review at an additional meeting of the AEC. The resulting additional meeting may be cancelled if the required Committee quorum is not achieved. The AEC are not obliged to be available for an additional meeting. *Note*: Missing the deadline for a scheduled meeting **will not be** considered exceptional circumstances.

Human Research Ethics Committee Approval

All those involved in Human Research must demonstrate familiarity with the latest version of the National Statement on Ethical Conduct in Human Research and its application to their research.

Researchers designing a research project should read the National Statement on Ethical Conduct in Human Research, noting in particular Chapter 3.1, The Elements of Research Design, and other sections relevant to their project.

Chapter 3.1 of the National Statement on Ethical Conduct in Human Research outlines seven elements that provide guidance on the ethical considerations that are relevant to the way that research is designed, reviewed and conducted. These Elements are:

- Element 1 Research Scope, Aims, Themes, Questions and Methods
- Element 2 Recruitment
- Element 3 Consent
- Element 4 Collection, Use and Management of Data and Information
- Element 5 Communication of Research Findings or Results to Participants
- Element 6 Dissemination of Research Outputs and Outcomes
- Element 7 After the Project

Researchers planning to do any type of research involving Aboriginal and Torres Strait islander peoples must consult and follow the advice in the current versions of:

- Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders and Keeping research on track II
- *AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research* produced by the Australian Institute of Aboriginal and Torres Strait Islander Studies.

These guides embody the best standards of ethical research and human rights and seek to ensure that research with and about Aboriginal and Torres Strait Islander peoples, and research which draws on their traditional

knowledge, follows a process of meaningful engagement and reciprocity between the researcher and the individuals and/or communities involved in the research.

A project requires Human Research Ethics approval prior to commencement if it involves the collection or use of human data, i.e. human participation. As per the National Statement Human participation may include:

- taking part in surveys, interviews or focus groups;
- undergoing psychological, physiological or medical testing or treatment;
- being observed by researchers;
- researchers having access to their personal documents or other materials;
- the collection and use of their body organs, tissues or fluids (eg skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens) or their exhaled breath;
- access to their information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database.

Researchers must review submission deadlines and meeting dates available on the Federation University Research Ethics website to determine the most appropriate submission date for their application.

Researchers should complete the following steps to gain HREC approval for any work involving humans or human data.

	ACTIVITY	**RESPONSIBILITY**	**STEPS**
1.	Project risk assessment	Chief Investigator Co-Researchers	Assess the project's level of ethical risk by reviewing the definition of risk outlined in the National Statement. Supervisors will, in consultation with HDR candidates, Masters by Coursework and Honours students, ensure that the appropriate category of risk is identified.
2.	Download and complete a new application form. The form can be found on the Research Ethics website.	Chief Investigator Co-Researchers	Select and complete the Human Research Ethics Application Form from the Federation University Research Ethics website. Ensure the application form is fully completed and authorised by the Chief Investigator and any other researchers listed on the application. The Ethics Office can be consulted with regard to administrative aspects of an application and queries related to risk assessment. Supervisors will mentor research students throughout the development of the ethics

			application and will provide guidance throughout the process.
3.	Attach supplementary documentation	Chief Investigator Co-Researchers	Attach copies of any required supplementary documentation. Examples of documentation that may be required: • Recruitment material, including advertisements, emails, phone scripts, etc. • Plain Language Information Statement (PLIS) • Consent form • Data collection tools such as questionnaires, interview schedules, focus group guides • Debriefing material • Other required approvals or supporting documentation.
4.	Obtain approval from relevant Institute/Centre/other authority	Chief Investigator Co-Researchers	Applications must be signed by the: • Chief Investigator, and • All Co-Researchers Applications should then be reviewed, and approved for submission to the HREC by one of the authorised personnel listed on the form and/or Federation University Research Ethics website. *Note:* In the case of an application for a student research project, the Principal Supervisor must sign off as the Chief Investigator and, as Chief Investigator, is responsible for the project conduct.
5.	Submit application for HREC review	Chief Investigator Co-Researchers	Submit completed and fully authorised copy of the application, plus all attachments, (in word.doc format or pdf format) as per the submission method and deadlines detailed on the Research Ethics website for presentation at the relevant HREC meeting. • Ensure application has been reviewed and includes all required signatures.

			• Submit the completed application, including all attachments, to the Ethics Office as per the submission method detailed on the Research Ethics website. Researchers are responsible for follow-up with an email or phone call prior to the Agenda Due Date to obtain the Project Number & Meeting Number if they have not otherwise been advised by the Ethics office that the application has been accepted. *Note: Late submissions will be carried over to the next appropriate meeting without exception.*
6.	Outcome notification	Ethics Office	The Ethics Office will contact the Chief Investigator advising of the outcome of the meeting. *Note:* projects must not commence until full approval has been received.

HREC Out of Session Application Process

Researchers should complete the following steps to gain HREC approval for Out of Session Reviews:

	STEPS	**WHO IS RESPONSIBLE?**	**COMMENTS**
1.	Out of Session application review	Chief Investigator Co-Researchers	Consideration of an ethics application with an urgent deadline is available under exceptional circumstances. Out of Session reviews are not standard practice, and will not be considered for applicants who have missed a prior meeting deadline. In the case of exceptional or extenuating circumstances, requests for Out of Session reviews should be directed in the first instance to the Ethics Office.

	Request is considered	HREC Chair	The Chair HREC will determine if the application will be considered for an Out of Session review. For above low risk projects, quorum for the HREC Out of Session review must be achieved to finalise the review of the application. There may be cost implications for researchers.

HREC Projects Approved by another Australian Human Research Ethics Committee (HREC) Application Process

As per the National Statement, Federation University has a responsibility to reduce or eliminate duplication of ethical review. As such Federation University Australia Human Research Ethics Committee recognises approvals from other Australian Human Research Ethics Committees and may endorse such approval in certain circumstances, such as when a researcher is involved in a collaborative project hosted by another institution. The HREC will also consider the approval of projects transferred from another institution by a new staff member.

Researchers should complete the following steps to apply for HREC endorsement for projects approved by another Australian Human Research Ethics Committee.

Recognition of External Approval

Projects where the Federation University staff member is part of a collaborative project hosted by another institution:

	ACTIVITY	**RESPONSIBILITY**	**STEPS**
1.	Complete and submit the Externally Approved Application form, selecting 'externally approved', and submit it to the Ethics Office as per the submission method detailed on the Research Ethics website.	Federation University Chief Investigator *Note*, the overall project lead/ Chief Investigator may be a different person based at another institution	A copy of the original application (including attachments) and notice of approval from the external HREC must be submitted to the Ethics Office.
2.	Consideration of application	HREC Chair	The Ethics Office will review the application and advise the Chair of any potential issues.
3.	Chair Approval	HREC Chair	The Chair, HREC signs off on the endorsement of external approval.
4.	Notification of outcome	Ethics Office	The Ethics Office will advise the applicant of the outcome.

Transfer of Approval

Projects transferred from another institution by the Chief Investigator, who is a new member of staff:

	ACTIVITY	RESPONSIBILITY	STEPS
1.	Complete and submit the Externally Approved Application form, selecting 'transfer', and submit it to the Ethics Office as per the submission method detailed on the Research Ethics website.	Chief Investigator Co-Researchers	A copy of the original application (including attachments) and notice of approval from the external HREC must be submitted to the Ethics Office, Research Services.
2.	Consideration of application	HREC Chair	The Chair of the HREC will review the application and advise whether the approval is endorsed by the University, or the project requires new approval, requiring submission of a completed application.
3.	Notification of outcome	Ethics Office	The Ethics Office will advise the applicant of the outcome.

Institutional Biosafety Committee Approval

Institutional Biosafety Exempt and Notifiable Low Risk Dealings (NLRDs)

Every dealing with a GMO will need to be licensed by the Gene Technology Regulator, unless the dealing is an exempt dealing, a notifiable low risk dealing NLRD or on the Register of GMOs.

Exempt dealings:

- Exempt dealings are those that pose little or no risk.
- There will be no exemptions for any release of a GMO into the environment.
- Exempt dealings must be conducted in accordance with Australian Standard AS/NZS 2243.3:2002 (Safety in laboratories: microbiology) for Physical Containment Level 1

Notifiable low risk dealings (NLRDs):

- NLRDs are dealings with GMOs which are very low risk and which may proceed provided that certain conditions spelt out in the regulations are observed.
- This will include requirements that the specified dealings be undertaken only in contained facilities PC2.
- NLRDs must be submitted to the IBC for assessment. A record of all NLRDs will be kept.
- Work on the Dealing may not commence until approval by the IBC has been received.
- The Gene Technology Act does not allow dealings which involve the intentional release of a GMO into the environment to be prescribed as a NLRD.

Licences

All dealings with GMOs (that are not exempt or NLRDs) will need to be licensed by the Regulator. There are two forms of licences - Dealings Not Involving Intentional Release (DNIR) and Dealings Involving an Intentional Release (DIR).

The licensing system will be based on rigorous scientific risk assessment and extensive consultation with expert advisory committees, Government agencies and the public for releases of GMOs into the environment.

These must be submitted to the IBC for assessment. The IBC then transmits the "Dealing" to the OGTR for approval.

Work must not commence on these dealings until a licence has been issued by the OGTR. Approval from the OGTR may take up to 90working days.

The following table outlines the categories of dealings and the type of approval required:

Category	OGTR Licence required	Containment
Exempt (ED)	No, but consult IBC	No intentional release to the environment
Notifiable Low Risk Dealing NLRD	No, dealings must be assessed by IBC; notified in annual report	Yes PC1 or PC2 (usually)
Dealings Not involving Intentional Release (DNIR)	Yes, applications must be reviewed by IBC; RARMP prepared and licence decision by the Regulator	Yes ≥ PC2 (usually) and other conditions will apply
Dealings involving Intentional Release (DIR) (except for limited and controlled releases)	Yes, applications must be reviewed by IBC; consultation on application, RARMP prepared, consultation on RARMP and licence decision by the Regulator	Containment measures may be required, determined on a case-by-case basis, and other licence conditions will apply
Dealings involving Intentional Release (DIR) (limited and controlled)	Yes, applications must be reviewed by IBC; RARMP prepared, consultation on RARMP and licence decision by the Regulator	Containment measures will be required based on size/scope of release sought by applicant; and other licence conditions will apply
Inadvertent dealing	Yes, licence decision by the Regulator only for the purposes of disposal of the GMO	Containment and/or disposal measures will apply
GMO Register	No, but must be previously licensed; review of related RARMPs	Containment measures may be required
Emergency Dealings Determination (EDD)	No, determination by the minister, subject to advice of threat and utility of GMO from competent authorities and risk assessment advice from the Regulator	Containment and/or disposal measures may be included in EDD conditions

Institutional Biosafety Committee Application Process

A project involving the use of GMOs cannot proceed without official written approval from the IBC and/or a licence from the OGTR.

When the application has been reviewed by the IBC, the applicants will receive notification from the IBC.

Researchers should complete the following steps to gain IBC and OGTR approval:

Exempt Dealings (ED):

	ACTIVITY	RESPONSIBILITY	STEPS
1.	Contact Ethics Officer or Secretary, IBC	Principal Researcher	Contact the Ethics Officer or the Secretary, IBC for advice on whether the project can be considered Exempt.
2.	Complete Exempt Dealing notification form	Principal Researcher	Details of the project should be recorded on the Exempt Dealing application form. This form will then be kept on record within Research Services.
3.	Obtain IBC declaration	Ethics Officer IBC Chair	The application for an Exempt Dealing should be signed off by the IBC Chair, who declares that the dealing is exempt in accordance with the Gene Technology Regulations.

Notifiable Low Risk Dealings NLRD:

	ACTIVITY	RESPONSIBILITY	STEPS
1.	Contact Ethics Officer or Secretary, IBC	Principal Researcher	Contact the Ethics Officer or the Secretary, IBC for advice on whether the project can be considered as an NLRD
2.	Complete NLRD application form	Principal Researcher	Details of the project should be recorded on the NLRD application form. Signatures of all researchers are required.
3.	Submit to a meeting of the IBC	Principal Researcher	The application for an NLRD should be submitted to a meeting of the IBC, who will consider whether the application meets the requirements of an NLRD. If the application is approved by the IBC, it is then signed off by the IBC Chair, who declares that the dealing is an NLRD in accordance with the Gene Technology Regulations.
4.	Provide applicant with outcome of meeting	Ethics Officer	The Ethics Officer will inform the applicant of the outcome of the meeting. The project will be approved unless further information is required, or the IBC

			have classified the project as another type of dealing.
5.	Enter NLRD on record	Ethics Officer	The Ethics Officer will enter the details of the NLRD on record, and provide the details to the OGTR via the annual reporting process each year.

For Dealings Not Involving Intentional Release (DNIR) & Dealings Involving Intentional Release (DIR):

	ACTIVITY	**RESPONSIBILITY**	**STEPS**
1.	Contact Ethics Officer or Secretary, IBC	Principal Researcher	Contact the Ethics Officer or the Secretary, IBC for advice on whether the project can will be considered an DNIR or an DIR
2.	Complete appropriate application form	Principal Researcher	Details of the project should be recorded on the appropriate application form, which are provided online from the OGTR. https://www.ogtr.gov.au/apply-gmo-approval Signatures of all researchers are required.
3.	Submit to a meeting of the IBC	Principal Researcher	The application for a DNIR or DIR should be submitted to a meeting of the IBC, who will consider whether the application meets the requirements of a DNIR or a DIR.
4.	Provide applicant with outcome of meeting	Ethics Officer	The Ethics Officer will inform the applicant of the outcome of the meeting. The project will be approved unless further information is required, or the IBC have classified the project as another type of dealing. The application should then be signed off by the IBC Chair. Following this, authorisation should be sought from the DVC (R&I).
5.	Submit complete application to the OGTR	Ethics Officer	The Ethics Officer will submit the complete application to the OGTR, who will acknowledge the

			application and assign a DNIR or DIR identification number.
6.	OGTR consultation timeframes	OGTR	For DNIR applications – 90 working days For DIR applications – 150 to 255 working days
7.	Decision on licence	OGTR	The OGTR makes a decision to issue, or refuse to issue, a licence, and the applicant will be advised.
8.	Decision is recorded on the public GMO record	OGTR	The decision on the licence application is recorded in the GMO Record on the OGTR website.

Certification of Facilities (IBC)

	ACTIVITY	**RESPONSIBILITY**	**STEPS**
1.	Planning a new facility (laboratory, plant and animal, etc)	University staff member	Certain work with GMOs must only be undertaken in facilities that are certified by the Regulator. The legislation allows the Regulator to certify physical containment (PC) facilities to ensure that appropriate standards are met for containment of GMOs and that trained and competent staff are carrying out procedures and practices. Any personnel planning a new facility must contact the Ethics Officer and the Chair IBC to be guided through the OGTR's certification process. The Regulator has issued guidelines specifying the requirements for certification of each of each type of facility to PC containment levels 1, 2, 3 or 4, which must be met before a facility can be certified.
2.	Inspection of new facilities	IBC	All facilities must be inspected before certification and annually thereafter (except those certified as a PC1 facility).
3.	Certification of facilities	OGTR	PC facilities are classified according to levels of stringency

			of measures for containing GMOs. The classifications relate to the structural integrity of buildings and equipment uses as well as to the handling practices employed by those working in the facility. 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.

New Application Review Outcomes (all committees)

As per detail above:

- a teaching program or research project involving the use of animals cannot proceed without official written approval from the AEC.
- research involving human participants cannot proceed without official written approval from the HREC.
- research involving GMOs cannot proceed without official written approval from the IBC.

After review by the relevant compliance committee, each application will be assessed with one of the following outcomes:

OUTCOME	DESCRIPTION AND REQUIRED ACTION
Approved	Full approval (Approved) allows the applicants to commence the teaching program or research project on the commencement date outlined in the notification. Adherence to the Standard Conditions of Approval is mandatory to maintain approval status.
Approved with Comment	Approved with Comment is deemed as full approval and allows the applicants to commence the teaching program or research project on the commencement date outlined in the notification. Adherence to the Standard Conditions of Approval is mandatory to maintain approval status. Applicants should note the comments made by the Committee.
Provisional Approval	Applicants must address the provisions outlined in the notification, using a copy of the notification as a cover sheet. The response to each of the issues raised should be addressed point by point, clearly explaining how each of the matters have been addressed in the application and/or supporting documents. A response merely stating that the relevant issues have been addressed in the application/documentation is not acceptable. The applicants should also supply a copy of any amended documentation, or supporting documentation requested by the Committee. Any changes made should be highlighted for easy identification and review by the Committee.

	Applications should be resubmitted within three months of receipt of the outcome of the initial review. If the application cannot be resubmitted within three months, either: • a new application will be required; or • a request submitted to the Ethics Office PRIOR to the three month deadline explaining extenuating circumstances and requesting an extension. If this request is not approved, the researchers must respond or resubmit on time, or a new application will be required. For projects requiring AEC approval, the Committee Chair will determine whether approval is required from the full Committee or Executive Committee, and whether the former can be determined by circulation. For projects requiring HREC approval, resubmissions will be assessed by either the Ethics Office or Committee Chair or both, as applicable. Projects must not commence until full approval has been received in writing from the Ethics Office.
Approval Withheld	Applicants must address the issues outlined in the notification and resubmit their application to for further review by the relevant committee, noting submission deadlines on the Federation University Research Ethics website. The response to each of the issues raised should be addressed point by point, clearly explaining how each of the matters have been addressed in the application and/or supporting documents. A response merely stating that the relevant issues have been addressed in the application/documentation is not acceptable. The applicants should also supply a copy of all supporting documentation, including any additional documents requested by the Committee. Any changes made should be highlighted for easy identification and review by the Committee. Applications should be resubmitted within three months of receipt of the outcome of the initial review. If the application cannot be resubmitted within three months, either: • a new application will be required; or • a request submitted to the Ethics Office PRIOR to the three month deadline explaining extenuating circumstances and requesting an extension. If this request is not approved, the researchers must respond or resubmit on time, or a new application will be required. The Committee will assess the applicants' response to the issues raised and a notification of outcome will be issued, as per the new application process. *Note:* Review of the revised withheld application may result in new concerns and new queries being raised by the Committee. Should this occur, they will be listed on the new Outcome Notification.
Not Approved	The relevant review Committee considers the issues regarding the project are of such significance that the project cannot proceed in its current form.

	The applicant will be provided with information as to why the Committee rejected the application. Should they choose to pursue the initial research, applicants are required to submit a new application for review at a subsequent meeting, noting submission deadlines available on the Federation University Research Ethics website. The new application will need to be significantly superior to the original application and address the major issues outlined in the Not Approved notification. The Committee will assess the new application, without reference to the original application, as per the standard process. Applicants are encouraged to contact the Ethics Team to arrange consultation regarding the new project with either the Ethics Team or members of the Committee.

Standard Conditions of Approval

The conduct of each approved project must comply with the Standard Conditions of Approval, relevant guides and legislation, and any specific conditions imposed by the relevant Committee.

Failure to comply with relevant guides/legislation, with Conditions of Approval, and any specific conditions mandated by the Committee, may result in suspension or withdrawal of approval and/or disciplinary action under the Research and Research Training Policy, and Research Integrity and Misconduct Procedure.

Process to Amend Approved Project (all committees)

Researchers should complete the following steps to gain Committee approval for proposed Project Amendments. Amendments will not be granted for projects without current approval, for example expired discontinued, or otherwise closed off projects.

	ACTIVITY	RESPONSIBILITY	STEPS
1.	Download and complete the Request for Amendments form. The form can be found on the Research Ethics website.	Chief Investigator Co-researchers	This form is to be used for: • Any proposed change(s) to an existing project • An extension request for an existing project • A change of personnel for an existing project Amendment Request forms should include: • Researcher/s name and details • Project title • Detailed information in relation to the proposed amendments.
2.	Attach copies of any supplementary documentation required for this amendment.	Chief Investigator Co-researchers	Any documents that have been amended should be attached to

			the Amendment Request. These may include, but are not limited to: • Public facing documentation • Data collection tools • External permissions Amended documents should be clearly marked with highlighting or tracked changes.
3.	Review Amendment Request	Chief Investigator	Amendment must be reviewed and approved by the Chief Investigator.
4.	Submit completed and signed Request for Amendments to the Ethics Office as per the submission method detailed on the Research Ethics website.	Chief Investigator Co-researchers	Amendment requests should be signed by all members of the research/project team.
5.	Review Amendment Request	Ethics Team Committee Chair Executive Committee Committee	The Request for Amendments will be reviewed by Ethics Team, Committee Chair, Executive Committee or full Committee, as applicable and researchers will be notified by the Ethics Office of the outcome.

Reporting and Monitoring

Reporting on Projects approved by the Animal Ethics Committee

The Australian Code for the Care and Use of Animals for Scientific Purposes requires Animal Ethics Committees to monitor research projects for which they have given ethical approval to ensure that they confirm to the protocol approved. Any changes to the approved project will require Committee approval.

The principal reason for monitoring research projects in accordance with the Code is to ensure that the activity does not jeopardise the wellbeing of animals.

Animal Ethics Incident Reports

	ACTIVITY	**RESPONSIBILITY**	**STEPS**
1.	Incident Report (if applicable)	Principal Researcher Research Team	Incidents, adverse effects and unforeseen events must be reported immediately to the Ethics Team, Research Services via the Incident Report Form downloadable from the Federation University Research Ethics website.

			Failure to do so will result in discontinuation of approval and/or disciplinary action. Principal Researchers are responsible for ensuring incidents are reported. Principal Researchers must provide details of steps (proposed or taken) to mitigate the effects of such incidents.

Animal Ethics Annual Reports

	ACTIVITY	RESPONSIBILITY	STEPS
1.	Annual Reports	Principal Researcher Research Team	It is a condition of approval that the Principal Researcher submits an annual report at the beginning of each year (prior to 15 January) from project commencement unto the conclusion of the project. The report must be submitted on the relevant template, downloadable from the Federation University Research Ethics website, must be signed by all applicants, and provide the following information: • Details of progress to date; • Maintenance and security of records; • Compliance with the approved protocol; • Compliance with any conditions of approval; • Details of any unexpected adverse effects of the research on animals which may have occurred (as previously reported on Adverse Incident report form) and of; • Steps taken to deal with these (as previously reported on Adverse Incident report form); • Changes in the research protocol (as previously reported on Amendment form); and • Any other problems relating to the conduct of the research. Failure to complete and return an annual report by the due date may

			lead to suspension or withdrawal of ethics approval.

Animal Ethics Final Reports

	ACTIVITY	RESPONSIBILITY	STEPS
1.	Final Report	Principal Researcher Research Team	It is a condition of approval that the Principal Researcher submits a final report, downloadable from the Federation University Research Ethics website, within one month of completion/ discontinuation of a project. This final report will include: • A summary of the results of the project; • Whether the aims of the project were achieved; • Maintenance and security of records; • Compliance with the approved protocol; and • Compliance with any conditions of approval. The final report must also contain: • Details of any unexpected adverse effects of the research on animals which may have occurred (as previously reported on Adverse Incident report form); • Steps taken to deal with these (as previously reported on Adverse Incident report form); • Changes in the research protocol (as previously reported on Amendment form); and • Any other problems relating to the conduct of the project. Failure to complete and return a final report by the due date may lead to suspension or withdrawal of ethics approval.

Auditing of Approved Projects

In line with the Code, the AEC will conduct internal auditing in relation to approved projects. The internal audit process may be carried out in a variety of ways:

- Researchers may be invited to attend a meeting of the Animal Ethics Committee to discuss their project and annual report, to provide evidence of the work they have completed to date including documentation and to answer any queries the Committee might have regarding the project;
- A representative of the AEC may visit field sites, housing facilities and laboratories to inspect facilities;
- In addition to discussing the conduct of a project with the researchers, the audit team may inspect facilities for storing data securely, examine the way data is being maintained including who has access, and consider the way risk and any unexpected outcomes have been managed in the project.

Reporting on Projects approved by the Human Research Ethics Committee

The National Statement requires Human Research Ethics Committees HREC to monitor research projects for which they have given ethical approval to ensure that they conform to the approved protocol. Any changes to the approved project will require Committee approval.

Human Ethics Incident Reports

	ACTIVITY	RESPONSIBILITY	STEPS
1.	Incidents and adverse events	Chief Investigator	Incidents, adverse events and unforeseen events must be reported immediately to the Ethics Team, Research Services. For example: Serious or unexpected adverse effects on participants and unforeseen events that might affect continued ethical acceptability of the project. Failure to do so will result in a review of the ethics approval and may lead to discontinuation of approval and/or disciplinary action. Principal Researchers are responsible for ensuring incidents are reported. Chief Investigator must provide details of steps, (proposed or taken) to mitigate the effects of such incidents.

Human Ethics Annual Reports

	ACTIVITY	RESPONSIBILITY	STEPS
1.	Annual Reports	Chief Investigator	It is a condition of approval that the Chief Investigator submits an annual report, which is to be

			submitted to the Coordinator, Research Ethics. The report must be made on the appropriate form, downloadable from the Federation University Research Ethics website, signed by all investigators and provide the following information: • details of progress to date; • maintenance and security of records; • compliance with the approved protocol; • compliance with any conditions of approval; • details of any serious or unexpected adverse effects of the research on participants which may have occurred; • steps taken to deal with these; • changes in the research protocol; and • any other problems relating to the conduct of the project. It is the Chief Investigator's responsibility to submit the report within 12 months of project commencement and annually thereafter. Failure to complete and return an annual report by the due date may lead to suspension or withdrawal of ethics approval.

Human Ethics Final Reports

	ACTIVITY	RESPONSIBILITY	STEPS
1.	Final reports	Chief Investigator	It is a condition of approval that the Chief Investigator submits a final report, downloadable from the Federation University Research Ethics website, within one month of completion/ discontinuation of a project. This final report will include: • a summary of the results of the project;

			• whether the aims of the project were achieved; • maintenance and security of records; • compliance with the approved protocol; and • compliance with any conditions of approval. The final report must also contain: • details of any serious or unexpected adverse effects of the research on participants which may have occurred (as previously reported on Adverse Incident report form); • any steps taken to deal with these (as previously reported on Adverse Incident report form); • changes in the research protocol (as previously reported on Amendment form); • any other problems relating to the conduct of the project. Failure to complete and return a final report by the due date may lead to suspension or withdrawal of ethics approval.

In line with the *National Statement,* the HREC has determined that all approved projects are subject to auditing as per the details outlined in the National Statement.

IBC Monitoring Inspections

	ACTIVITY	**RESPONSIBILITY**	**STEPS**
1.	Monitoring Inspections (with prior notification)	OGTR Licence or Certification Holders	Each year, the OGTR routinely conducts monitoring inspection to ensure that Licence and Certification holders are complying with the Gene Technology Act 2000 (the Act) and it subordinate legislation. The OGTR will make appointments to inspect certified Physical Containment (PC) facilities and dealings conducted in those

			facilities including: DNIRs and NRLDs.
2.	‘Spot’ checks (unannounced)	OGTR Licence or Certification Holders	A number of unannounced ‘spot’ checks will be conducted throughout the year to ensure that compliance is maintained at all times.

Suspension or Discontinuation of Approved Projects

	ACTIVITY	RESPONSIBILITY	STEPS
1.	Discontinuation or Suspension of an approved research project	Chair of the relevant Committee	Where the Chair of the relevant Committee is satisfied that circumstances have arisen such that a research project is not being or cannot be conducted in accordance with the approved protocol, including any conditions of approval, the Committee may withdraw approval and recommend that the research project be discontinued, suspended or that other necessary action be taken.
2.	Cease research project	Researchers	Researchers must not continue the research if ethics approval has been withdrawn and must comply with any special conditions required by the Committee.

Complaints and Appeals

Complaints or concerns relating to Research Integrity/Misconduct should be submitted in accordance with the Research Integrity and Misconduct Procedure.

Complaints concerning the care and use of animals

Complaints concerning the care and use of animals by the institution, including conscientious objection in the case of teaching activities

In the event that a person is dissatisfied with the use of animals in a particular experiment or teaching exercise, the following procedures are to be followed:

	ACTIVITY	RESPONSIBILITY	STEPS
1.	Submission of complaint	Aggrieved person	A written submission detailing the reasons for dissatisfaction is to be

			submitted by the aggrieved person to the AEC.
2.	AEC considers complaint and provides response	Ethics Office forwards complaint to AEC AEC	The AEC must consider the matters raised in the submission and respond in writing to those matters within 10 working days. The AEC may confirm or alter any decision previously made in relation to the relevant research proposal or proposed use of animals in research or teaching by special meeting.
3.	Aggrieved person considers response and accepts response or refers to Provost	Aggrieved person	If the aggrieved person is not satisfied with the AEC's written response, they may advise the Provost in writing that they have an irreconcilable difference with the AEC and must append a copy of both the submission forwarded to the AEC and the written response from the AEC.
4.	Provost reviews matter (if required)	Provost	In reviewing the matter referred, the Provost may invite the participation of an appropriately experienced person external to the University or member of an animal ethics committee external to the University or any other persons to assist in the deliberations.
5.	Provost provides advice	Provost	The Provost will provide written advice to both the AEC and the aggrieved person regarding the review of the matter. The Provost may require the AEC to reconsider their decision or procedures or may endorse the decision of the AEC.
6.	AEC considers advice of Provost	AEC	In the event that the AEC is required to reconsider their decision or procedures, the AEC must consider any advice given by the Provost.
7.	AEC makes final decision	AEC	Having considered any advice given by the Provost the AEC has ultimate authority for making a final decision on the matter referred.

Complaints concerning the process for independent external review of the AEC

The activities of the AEC undergo an independent external review every four years. The review is undertaken by The Department of Economic Development, Jobs, Transport and Resources (DEDJTR).

Should a researcher or the AEC have a complaint or concern in relation to the process followed or the outcome of the review, the Ethics Office should be contacted in the first instance. The following procedures will be followed:

	ACTIVITY	RESPONSIBILITY	STEPS
1.	Submit complaint	Aggrieved person	If required, a written submission detailing the complaint or concern is to be submitted by the aggrieved person to the Ethics Officer.
2.	Ethics Office refers complaint to Provost	Ethics Office	The complaint or concern will be referred to the Provost for consideration. After this consideration, the Provost may write to DEDJTR with a request that they revisit the area of concern.
3.	Provost provides advice	Provost	The Provost will provide written advice to the AEC/aggrieved person regarding the review of the matter.

Non-compliance with the relevant Codes relating to the care and use of animals

Complaints or concerns relating to non-compliance involving the use of animals should be directed to the Chair of the Animal Ethics Committee (via the Ethics Office within Research Services) in the first instance. Where complaints or grievances identify instances of non-compliance with/breaches of:

- The Australian Code for the Care and Use of Animals for Scientific Purposes; or
- The Australian Code for the Responsible Conduct of Research, the following procedure will be followed:

	ACTIVITY	RESPONSIBILITY	STEPS
1.	Ethics approval suspended	AEC Chair	The AEC Chair will formally advise the Principal Researcher that ethical approval for the project has been suspended. If applicable, urgent animal welfare concerns will be identified and appropriate action is to be taken to alleviate animal suffering or distress.
2.	Research Integrity Office to be notified	AEC Chair	The complaint of non-compliance will be **immediately referred** to the Research Integrity Office by the AEC Chair for resolution

			under the provisions of the University's *Research Integrity and Misconduct Procedure*. Please note: Where complaints allege misconduct that falls outside the description of 'research misconduct' (as described in the Australian Code for the Responsible Conduct of Research) the complaint will be handled in accordance with institutional processes for dealing with other forms of misconduct.
3.	Relevant regulatory authorities will be advised	Research Integrity Coordinator	If required, the relevant regulatory authorities (e.g. NHMRC or ARC) will be advised upon receipt of the complaint.

Complaints concerning ethical conduct in human research

Complaints or concerns relating to the ethical aspects of a research activity should be directed to Ethics Office in the first instance. The following procedure is followed, as applicable:

	ACTIVITY	**RESPONSIBILITY**	**STEPS**
1.	Submission of complaint	Aggrieved person	Complainant submits their complaint or concern to the Ethics Office. In some cases complaints may be submitted to the research team. Complainants will be encouraged to submit concerns in writing, but are not required to do so.
2.	Incident Report form completed	Chief Investigator Ethics Office	With the assistance of the Ethics Office if required, Chief Investigator submits an Incident Report. Any ongoing recruitment should be halted until further notice from the Committee Chair.
3.	Complaint forwarded to HREC Chair for consideration	Ethics Office	The Ethics Office forwards the complaint or concern outlined in an Incident Report to the HREC Chair. The Chair, in consultation with the Ethics Office, Research team and complainant, as applicable, may determine that the issue can be resolved locally,

			in which case the issue moves to step 4, below. If the complaint may be considered a potential breach of the Australian Code for Responsible Research Conduct, the matter should be referred to the Research Integrity and Misconduct Procedure. If the complaint may otherwise result in legal action or reputational damage to the University, the Provost will be notified of the complaint and process moves to step 5, below.
4.	Chair considers complaint	Chair	The Chair (or a delegate of the Chair) considers the complaint, including, where necessary, reference to original approved protocol. If the complaint can be handled locally, the Chair, via the Ethics Team, will provide feedback to the Research Team on their handling of the matter. An Amendment Request may be required to alter the project in order to prevent recurrence. Process moves to step 7, below.
5.	Chair reports to the Provost	Chair	The Chair reports their finding to the Provost
6.	Investigation of complaint	Provost	The Provost orders the investigation of the complaint, if required, under the Staff Conduct Policy and/or the Code for the Responsible Conduct of Research procedures.
7.	Notification to the HREC	Ethics Office Provost	The Ethics Office or Provost, as applicable, will report on the status of an investigation to the HREC, as required.

Complaints concerning ethics administration and committee decisions

The National Statement requires that an institution establish procedures for receiving and promptly handling concerns or complaints from researchers about the consideration of their research protocol by an HREC. If a

researcher wishes to appeal the decision of the any Committee about their research project or express concerns about the ethics administration process, the following action would normally be taken.

	ACTION	RESPONSIBLE	COMMENTS
1.	Submission of complaint	Applicant	Complainant submits their complaint or concern in writing to the Ethics Office.
2.	Consideration of complaint	Chair Ethics Office Centre/Institute Director ADVCR	The Chair and the Ethics Office consider the complaint. The relevant Research Advisor, Centre/Institute Director or delegate may be consulted, if required. The Chair may refer the matter to the full Committee, should they deem this appropriate.
3.	Applicant advised of outcome	Ethics Office	The Ethics Office will advise the applicant of the outcome of the consideration of their complaint. If the complainant is not satisfied with the result, the matter will be referred to the DVC (R&I) for consideration.

Institutional Biosafety Compliance

A person who deals with a GMO without a licence is guilty of an offence (punishable under Section 32 of the Act) if:

a. the person deals with a GMO, knowing that it is a GMO
b. the dealing with the GMO by the person is not authorised by a GMO licence, and the person knows or is reckless as to that fact
c. the dealing with the GMO is not specified in an Emergency Dealing Determination, and the person knows or is reckless as to that fact
d. the dealing is not a Notifiable Low Risk Dealing, and the person knows or is reckless as to that fact
e. the dealing is not an Exempt Dealing, and the person knows or is reckless as to that fact and
f. the dealing is not included on the GMO Register, and the person knows or is reckless as to that fact.

Complaints or concerns relating to non-compliance involving the use GMOs should be directed to the Chair of the IBC (via the Ethics Officer within Research Services) in the first instance. The following procedure will be followed:

	ACTIVITY	RESPONSIBILITY	STEPS
1.	IBC approval suspended	IBC Chair	The IBC Chair will formally advise the Principal Researcher that approval for the project has been suspended. If applicable, urgent human or animal welfare

			concerns will be identified and appropriate action is to be taken.
2.	OGTR to be notified	IBC Chair	If required, the IBC Chair will contact the OGTR upon receipt of complaint.
3.	Research Integrity Coordinator to be notified	IBC Chair	The complaint of non-compliance will be **immediately referred** to the Research Integrity Coordinator and the DVC (R&I) by the IBC Chair for resolution under the provisions of the University's *Research Integrity and Misconduct Procedure*. Please note: Where complaints allege misconduct that falls outside the description of 'research misconduct' (as described in the Australian Code for the Responsible Conduct of Research) the complaint will be handled in accordance with institutional processes for dealing with other forms of misconduct.
4.	Relevant regulatory authorities will be advised	Research Integrity Coordinator	If required, the relevant regulatory authorities (e.g. NHMRC or ARC) will be advised upon receipt of the complaint.

Responsibility

Researchers must ensure that:

- no research is conducted which has not received approval by the AEC, HREC or IBC if and as applicable;
- all relevant information has been provided to the relevant Committee;
- all relevant guidelines and legal requirements are complied with;
- monitoring requirements are complied with;
- proposed protocol modifications and amendments are submitted to the relevant Committee for approval;
- incidents and adverse events are promptly notified.

Researchers are expected to declare:

- sources of funding;
- commercial sponsorship and/or involvement;
- relevant personal and/or competing interests, including consultancies, paid travel, shareholdings, patents or patent applications, etc.;
- any payments, inducements or rewards offered to research participants.

The Ethics Office is responsible for:

- Liaising with researchers, the HREC Chair and the HREC and Sub-committees;
- Providing executive support to the HREC;
- Informing researchers of the outcome of their application;
- Coordinating the annual and final reporting for approved projects;
- Collating annual reports for various Government departments;
- Reporting to Federation University Australia governing bodies, as required.

Each Committee is responsible for:

- Assessing and approving all applications in accordance with the relevant governing document;
- Monitoring approved applications throughout their lifecycle;
- Operating in accordance with the relevant guides, legislation and institutional policies and procedures;
- Notifying the DVC (R&I) of any potential issues relating to ethics in research in a timely manner.

Supporting Documents

- Research and Research Training Policy
- Research Integrity and Misconduct Procedure

Promulgation

The Research Ethics and Institutional Biosafety Procedure will be communicated throughout the University via:

1. an Announcement Notice under 'FedNews' website and through the University Policy - 'Recently Approved Documents' webpage to alert the University-wide community of the approved Policy;
2. inclusion on the University Policy, Procedure and Forms website; and/or
3. distribution of e-mails to Head of School / Head of Department / University staff.

Implementation

The Research Ethics and Institutional Biosafety Procedure will be implemented throughout the University via:

1. Information Sessions; and/or
2. Training Sessions.