Purpose

The purpose of this document is to outline the Federation University policy on Human and Animal Research Ethics, and Institutional Biosafety.

This policy will inform members of the University community of their obligations to conduct ethical research in accordance with the National Statement on Ethical Conduct in Human Research (2007), the Australian Code for the Care and Use of Animals for Scientific Purposes (8th Edition, 2013), and the Gene Technology Regulations (2001).

Scope

This policy applies to:
• All staff, including sessional staff, employed by the University or any controlled entity;
• All members of University ethics committees, including the Human Research Ethics Committee, the Animal Ethics Committee and the Institutional Biosafety Committee;
• All persons, including adjunct staff and honorary staff engaged in research under the auspices of the University or any controlled entity;
• All students of the University who engage in research and/or research related activities while enrolled at the University.

Legislative Context

National Statement on Ethical Conduct in Human Research (2007) incorporating all updates
Australian Code for the Responsible Conduct of Research, 2007
Gene Technology Act 2000
Gene Technology Regulations 2001

Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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</thead>
<tbody>
<tr>
<td>Animal Ethics Committee (AEC)</td>
<td>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.</td>
</tr>
<tr>
<td>Approved</td>
<td>A review outcome for a project approved to commence.</td>
</tr>
<tr>
<td>Approved with comment</td>
<td>A review outcome for a project that has been approved to commence, but with comment from the relevant Committee.</td>
</tr>
<tr>
<td>Approval Withheld</td>
<td>A review outcome for a project application which requires that ethical issues be satisfactorily addressed and the application resubmitted to the relevant Committee before the project can commence.</td>
</tr>
<tr>
<td>The Code</td>
<td>The Australian Code for the Responsible Conduct of Research.</td>
</tr>
<tr>
<td>Compliance</td>
<td>Acting in accordance with the relevant Code, National Statement and/or Regulation.</td>
</tr>
<tr>
<td>Co-Researcher/s</td>
<td>One or more participants (or a particular sub-group of participants) who make/s a significant contribution to the planning, design implementation or outputs of a research projects, including collection, analysis or interpretation of data.</td>
</tr>
<tr>
<td>Expedited Review</td>
<td>A special category of low risk application considered for review only by the HREC Sub-committee.</td>
</tr>
<tr>
<td>Gene Technology</td>
<td>Any technique for the modification of genes or other genetic material, but does not include:</td>
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<td></td>
<td>• sexual reproduction; or</td>
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<td></td>
<td>• homologous recombination; or</td>
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<td></td>
<td>• any other technique specified in the Gene Technology Regulations.</td>
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<td>Term</td>
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</table>
| Genetically Modified Organism (GMO)       | • An organism that has been modified by gene technology; or  
• 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  
• 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:  
• A human being, if the human being is covered only because the human being has undergone somatic cell gene therapy; or  
• 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 |
<p>| Please Note:                              | If any GMOs will be involved in the project, the researcher(s) must ALSO submit an application to the IBC.                                                                                               |
| 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.                                                |
| Human Research Ethics Sub-committee (HRESC)| A Sub-committee of the University Human Research Ethics Committee. This Committee only assesses Expedited Applications.                                                                                   |
| Human Participants                        | Research participants who are personally interacting with the investigator, subject to observation, and/or those whose personal and confidential records are being accessed                                           |
| 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.                                                       |
| Institutional Biosafety Committee (IBC)   | A University Committee established in accordance with the Gene Technology Regulations 2001 to assess, review, monitor and approve certain kinds of research involving genetically modified organisms. |
| Low Risk                                  | An Expedited Application presenting minimal ethical risk to participants (as outlined in the HREC Procedure).                                                                                               |
| Monitoring                                | The process of verifying that the conduct of research conforms to the approved proposal.                                                                                                               |
| NHMRC                                     | National Health and Medical Research Council.                                                                                                                                                               |
| Not Approved                              | A review outcome for a project that has not been given Committee approval to progress                                                                                                                     |
| Participant                               | Anyone who has given informed consent to participate in a research project.                                                                                                                                  |
| Project                                   | Any activity or group of activities that form a discrete piece of work that aims to achieve a scientific purpose.                                                                                             |
| Provisional Approval                      | A category review outcome for a project approved subject to particular issues being satisfactorily addressed as directed by the relevant Committee                                                          |</p>
<table>
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<tbody>
<tr>
<td>Risk</td>
<td>The function of the magnitude of harm and the probability that it will occur.</td>
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<tr>
<td>Standard Review</td>
<td>Standard application process for ethics approval.</td>
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<tr>
<td>Terms of Reference</td>
<td>Terms of Reference show how the scope of the Committees will be defined,</td>
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<td></td>
<td>developed, and verified.</td>
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<tr>
<td>Variation</td>
<td>Any proposed amendment or modifications researchers might wish to make to</td>
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<tr>
<td></td>
<td>an approved project. All variations require approval from the Committee.</td>
</tr>
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**Policy Statement**

In accordance with the Australian Code for the Responsible Conduct of Research, the University is obligated to provide a research governance framework through which research is assessed for ethical acceptability. This research governance framework is designed to ensure that research undertaken by the University is ethically designed, reviewed and conducted. The University’s research governance framework demands that its researchers comply with laws, regulations, guidelines and codes of practice governing the conduct of research.

The responsibilities of researchers under the various regulations and codes of practice include compliance with ethical principles, and:

- respect for, and protection of, human participants in research; and/or
- ethical and humane use and care of animals used in research.

Federation University adheres to and promotes the principles of ethical research as outlined in the National Statement on Ethical Conduct in Human Research (2007), the Australian Code for the Care and Use of Animals for Scientific Purposes (8th Edition, 2013) and the Gene Technology Regulations (2001).

Under these policy statements no research involving human participants, use of animals or genetically modified organisms can be undertaken without approval by the appropriate University Committee:

- Animal Ethics Committee (AEC)
- Human Research Ethic Committee (HREC)
- Institutional Biosafety Committee (IBC)

**Training**

As part of its obligations, the University will provide induction, formal training and appropriate continuing education covering ethics to all staff and research students.

**Mentoring of Students**

In accordance with their role as the Principal Researcher on relevant ethics applications, supervisors of Higher Degree by Research candidates and Honours students are responsible for mentoring their students and providing guidance throughout the relevant ethics application process. This includes the assessment of the approval type required, the development of an application, monitoring of work undertaken following approval, and submission of required reports.

Principal Researchers are also responsible for the long term storage of relevant research data and materials, including for student projects they oversee.

**Human Research Ethics**

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The University adheres to the National Statement on Ethical Conduct in Human Research (2007) which requires that researchers comply with ethical principles to ensure that research:

- has merit;
- is conducted with integrity;
- is just;
- has beneficence; and
- is conducted with respect.

The University’s Human Research Ethics Committee applies a set of principles outlined in the National Statement that govern the ethical conduct of research involving human participants. To ensure compliance with the various regulations and codes of practice relating to human research, the University requires that written approval from the Human Research Ethics Committee must be obtained when required so as to protect human participants in research.

**Ethical considerations in the Design, Development, Review and Conduct of Research**

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

The University acknowledges that research with Aboriginal and Torres Strait Islander peoples spans many methodologies and disciplines, and that there are wide variations in the ways in which Aboriginal and Torres Strait Islander individuals, communities and groups are involved in, or are affected by, research. Relevant research ethics applications must demonstrate compliance with the most contemporary 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* 11 as well as the *Guidelines for Ethical Research in Australian Indigenous Studies (GERAIS)* produced by the Australian Institute of Aboriginal and Torres Strait Islander Studies. These guidelines 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 follows a process of meaningful engagement and reciprocity between the researcher and the individuals and/or communities involved in the research.

The University will ensure that all staff and students who undertake research involving humans have access to the appropriate training required and that they are aware of their responsibilities.

**Requirements for Human Research Ethics Approval**

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Authorised by: Deputy Vice-Chancellor (Research & Innovation) | Document Owner: Director, Research Services | Original Issue: 25/11/2015 | Current Version: 11/01/2019 | Review Date: 05/10/2022 | Policy Code: RS1921

CRICOS Provider Number: 00103D

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A project requires Human Research Ethics approval if one or more of the following apply:

• it involves human participants;
• human consent is to be sought;
• human medical or electronic records are to be accessed;
• individual identifying information is to be collected or used;
• personal or culturally sensitive information is to be collected or used;
• individuals (or groups) could be disadvantaged as a result of participation; or
• information collected could have ethical, legal or commercial implications.

Projects Approved by Another Australian Human Research Ethics Committee (HREC)

Federation University Australia Human Research Ethics Committee recognises approvals from other Australian Human Research Ethics Committees and may endorse such approval upon provision of the appropriate information.

The Human Research Ethics Committee (HREC)

The HREC is established in accordance with National Health and Medical Research Council (NHMRC) requirements to oversee, approve and monitor research involving humans.

The Committee considers the ethical implications of proposed research involving human participants. This includes all research and teaching projects, including surveys, interviews, experiments, analysis of databases, and examination of documents, where the interests of human participants require consideration.

The Committee ensures ethical standards are addressed in research projects involving human subjects, in order to protect the interests of the research subjects, the investigator, the University and the general community, in accordance with the NHMRC’s National Statement.

The Committee acts to protect the confidentiality and privacy of individuals by ensuring the security, storage and disposal of confidential data collected during the conduct of research involving human subjects. The Committee acts to promote understanding within the University and the broader community of the ethical issues raised by research, teaching and related academic activities.

The Committee acts to inform and work with the Research Committee to ensure the adoption of, and compliance with, appropriate codes of practice for the conduct of research involving human subjects.

The Committee establishes, implements and reviews procedures for evaluating, certifying and monitoring the acceptable ethical conduct of research involving human subjects and conducted by:

1. staff and/or students of Federation University Australia on a campus, using Federation University Australia premises, equipment, name or resources (human and physical);

2. staff and/or students of Federation University Australia outside a campus using Federation University Australia equipment, name or resources (human and physical);

3. other persons, who are not staff and/or students of Federation University Australia, using Federation University Australia premises, equipment, name or resources (human and physical)

HREC Membership

Membership of the University HREC is in accordance with the National Statement.
HREC Applications

Standard Review

An application not considered to be in the low risk category, (which is a project presenting minimal ethical risk or less to participants - as outlined in the HREC Procedure), is considered by the full HREC Committee as a standard review, as outlined in the Human Research Ethics Procedure.

Bulk Review

An application can be considered under bulk review when the project is low risk, and involves multiple student researchers studying the same course. The student projects are incorporated under the umbrella of a standard application and are approved as amendments to the standard application where the students nominate which of the approved methodologies etc they will use. The umbrella standard application is considered by the full HREC Committee as a bulk standard review.

Expeditied Review

Where a project is assessed by the applicant (using the Risk Assessment Checklist) to be in the low risk category, an application can be approved outside of the full Committee meeting schedule. Assessment of risk and completion of the appropriate form is in accordance with the process outlined in the Human Research Ethics Procedure.

Out of Session Application Review

An application with an urgent deadline may be considered by the HREC in an Out of Session review only under exceptional circumstances. This will be at the discretion of the Chair of the Human Research Ethics Committee and may involve additional costs to the applicant.

Request for Approval to use Existing Data

In some circumstances, such as but not limited to, seeking to use existing data for a purpose other than that for which it was collected, or where required by the custodial body, the use of existing data may require HREC approval. Researchers are advised to consult Research Services to determine whether an application should be submitted.

HREC Monitoring and Auditing

The National Statement requires the HREC to monitor research projects for which they have given ethical approval in order to ensure that they conform to the protocol approved.

The principal reason for monitoring research projects is to ensure that their conduct does not jeopardise the rights and interests of those who have consented to participate and/or approved use of their personal information.

Monitoring involves the completion of an annual/final report form. Random audits of approved research activities may be undertaken by the University. In accordance with the National Statement, all approved projects may be subject to auditing by the HREC.

HREC Complaints and Appeals

1. Complaints concerning the HREC process of review of an application or report, including resolution of disagreements between HREC members, between the HREC and investigators, and between the HREC and the institution

Complaints will be dealt with in accordance with the University’s Applying for Human Research Ethics Procedure (Policy Code: RS1922).

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CRICOS Provider Number: 00103D
2. Complaints concerning the HREC process of review of an application or report, including resolution of disagreements between HREC members, between the HREC and investigators, and between the HREC and the institution

Complaints will be dealt with in accordance with the University's Research Integrity and Misconduct Procedure (Policy Code: RS1502).

Animal Research Ethics

All those people involved in the care and use of animals for scientific purposes must be aware of the relevant Commonwealth, state and territory legislation, including the Australian Code for the Care and Use of Animals for Scientific Purposes 8th edition 2013.

The purpose of the University's policy and procedure on ethics in research is to ensure the ethical conduct of good animal (non-human) research, in which animal care and use is ethical and humane. The University adheres to the Australian Code for the Care and Use of Animals for Scientific Purposes 8th edition 2013 which requires that researchers respect the animals they use in research. The code emphasizes the responsibilities of researchers and the University to:

- ensure that animal use is justified;
- ensure that the welfare of animals is always considered;
- promote the use of techniques that replace animal use;
- minimise the number of animals used;
- refine methods to avoid pain and distress in animals.

The University's Animal Ethics Committee (AEC) applies a set of principles outlined in the Australian Code for the Care and Use of Animals for Scientific Purposes 8th Edition (2013) that govern the ethical conduct of research involving the use of animals. To ensure compliance with the various regulations and codes of practice relating to animal research, the University requires that written approval from the Animal Ethics Committee must be obtained when required so as to protect animals used in research.

The University is responsible for ensuring that all persons involved in animal care and use are appropriately trained and competent, and that they maintain adequate records of animal usage.

Requirements for Animal Ethics Committee (AEC) Approval

All activities that involve the care and use of animals for scientific purposes must be subject to ethical review, approval and monitoring by the AEC.

Projects Approved by Another Australian AEC

Federation University AEC does not recognise approvals from other Australian AECs. Any projects that are transferred from another institution must apply for and receive approval from the Federation University AEC, although prior approval from another institution will be taken into consideration.

The Animal Ethics Committee

The primary function of the AEC is to consider the ethical implication of proposed research and teaching projects involving animals, conducted by staff and/or students of Federation University Australia. The Committee reviews all projects with activities involving animals, including acquisition, transport, breeding, housing, husbandry, trapping, observations, fieldwork, the use of the animal, and the provisions for the animal at the completion of their use.
The role of the AEC is to:

- ensure that the use of animals is justified;
- provide for the welfare of those animals;
- incorporate the principles of Replacement, Reduction and Refinement (Three R's);
- review and approve new and ongoing activities;
- monitor the housing, care and use of animals;
- take action regarding unexpected adverse events;
- take action regarding non-compliance;
- approve guidelines for the care and use of animals;
- provide advice and recommendations to the institution;
- report to the institution.

AEC Membership

The AEC is established as per the Australian Code for the Care and Use of Animals for Scientific Purposes 8th edition 2013.

AEC Applications

Standard Review

An application for ethical approval for a project involving animals is considered by the AEC as a Standard Review, as outlined in the Animal Ethics Procedure.

Urgent Application Review

An application with an urgent deadline may be considered by the AEC in an extraordinary meeting under exceptional circumstances. This will be at the discretion of the Chair of the AEC.

AEC Monitoring and Auditing

The conduct of approved activities is monitored by the AEC. This includes the monitoring of the care and use of animals by inspecting animals and animal housing, as well as regular assessment of acquisition, transport, breeding and husbandry of animals. The AEC is required to monitor any activities that are likely to cause distress to animals. The AEC is able to delegate authority to a suitably qualified member of staff, to monitor a project where appropriate, for example during fieldwork.

The AEC is required to maintain records of all inspections and monitoring of activities and report these to Government, as outlined in the Code. Random audits of approved activities may be undertaken by the University. In line with the National Statement, all approved projects may be subject to internal and external auditing.

AEC Complaints and Appeals

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

Complaints will be dealt with in accordance with the University’s Applying for Animal Research Ethics Procedure (Policy Code: RS1923).
2. Complaints concerning the AEC process of review of an application or report, including resolution of disagreements between AEC members, between the AEC and investigators, and between the AEC and the institution

Complaints will be dealt with in accordance with the University’s Applying for Animal Research Ethics Procedure (Policy Code: RS1923).

- 3. Complaints concerning the process for independent external review

Complaints will be dealt with in accordance with the University’s Applying for Animal Research Ethics Procedure (Policy Code: RS1923).

- 4. Non-Compliance with the relevant Codes (Research Misconduct)

Complaints will be dealt with in accordance with the University’s Research Integrity and Misconduct Procedure (Policy Code: RS1502).

Institutional Biosafety

The University adheres to the Gene Technology Act 2000 and the corresponding Gene Technology Regulations 2001. The purpose of the Act and corresponding Regulation is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs. The Act regulates all dealings (e.g. research, manufacture, production, commercial release and import) with live, viable organisms that have been modified by techniques of gene technology, including the progeny (or descendants) of such GMOs which also share a genetically modified trait. The legislation will also regulate some GM products, but only where the products are not regulated by an existing agency.

Institutional Biosafety Committee (IBC)

The purpose of the Institutional Biosafety Committee (IBC) is to assess, review and approve certain kinds of research related to Genetically Modified Organisms (GMOs). The Committee advises on the identification and management of the risks associated with dealings with GMOs undertaken by the organisation, including the containment of GMOs. The Committee also provides an interface with the Office of the Gene Technology Regulator (OGTR).

The IBC is responsible for conducting inspections of OGTR-certified facilities to ensure that they adhere to the Act and licensing agreements. Membership of the IBC is established as per the Gene Technology Regulations 2001.

The role of the IBC is to:

1. Undertake assessment, review and approval of research proposals, to identify any potential biohazard which may arise in the course of research as a consequence of any type of experiment or manipulation which:
   - May result in the liberation or creation of novel types of nucleic acid with the capacity to multiply or spread to involve humans, animals, or plants; or
   - Involves hazardous micro-organisms or potentially tumorigenic viruses; or
   - Involves the use of known or suspected teratogens and carcinogens.

2. Assess the actual and potential risks involved in the light of the intrinsic nature of the experiments, the competence of the personnel and the security of the laboratory facilities.
3. Determine containment and procedures for experimental work under its purview, and for the housing, storage and transportation of genetically manipulated organisms;

4. Inspect and certify relevant facilities as specified in the Act, before they are used for genetic manipulation work (at least annually);

5. To advise researchers on matters related to GMOs.

IBC Monitoring

An appropriately qualified member of the IBC shall, on behalf of the University, inspect all of the University's relevant research facilities, against the Regulator's requirements for containment, at least once per year.

The Regulator may undertake monitoring, including auditing of written reports or unannounced site visits, at their discretion.

IBC Complaints and Appeals

1. Complaints concerning the IBC process of review of an application or report, including resolution of disagreements between IBC members, between the IBC and researchers, and between the IBC and the institution

Complaints will be dealt with in accordance with the University's (to be developed) Institutional Biosafety Approval Procedure (Policy Code: RS....).

2. Non-Compliance with the relevant Codes (Research Misconduct)

Complaints will be dealt with in accordance with the University's Research Integrity and Misconduct Procedure (Policy Code: RS1502).

Supporting Documents

Applying for Animal Research Ethics Procedure
Applying for Human Research Ethics Procedure
Research Integrity Policy
Research Integrity and Misconduct Procedure
Staff Code of Conduct

Institutional Biosafety Approval Procedure (to be developed)

Responsibility

- Deputy Vice-Chancellor (Research & Innovation) (as the Approval Authority) is responsible for monitoring the implementation, outcomes and scheduled review of this policy and its accompanying procedure(s).
- Director – Research Services (as the Policy Sponsor) is responsible for maintaining the content of this policy as delegated by the DVC (R&I).
- Research Services is responsible for the administration support for the maintenance of this policy as directed by the DVC (R&I).
Promulgation

The Ethical Conduct of Research Policy will be communicated throughout the University community in the form of:

1. an Announcement Notice via FedNews website and on the ‘Recently Approved Documents’ page on the ‘Policies, Procedures and Forms @ the University’ website to alert the University-wide community of the approved Policy;

Notification to Schools

Implementation

The Ethical Conduct of Research Policy will be implemented throughout the University via:

1. an Announcement Notice via FedNews website and on the ‘Recently Approved Documents’ page on the ‘Policies, Procedures and Forms @ the University’ website to alert the University-wide community of the approved Policy;

2. Staff induction sessions

3. Training sessions

Records Management

<table>
<thead>
<tr>
<th>Title</th>
<th>Location</th>
<th>Responsible Officer</th>
<th>Minimum Retention Period</th>
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</thead>
<tbody>
<tr>
<td>HREC Application Form</td>
<td>Research Services</td>
<td>Director, Research Services</td>
<td>7 years</td>
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<tr>
<td>HREC Approval Notification Form</td>
<td>Research Services</td>
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<td>Final Project Report Form</td>
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<td>Project Incident Report Form</td>
<td>Research Services</td>
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<tr>
<td>Complaints/Misconduct Report Form</td>
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<td>Exempt Dealing Application</td>
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<td>7 years</td>
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<tr>
<td>Proposal for Notifiable Low Risk Dealings (NLRDs)</td>
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