Laws, regulations and guidelines supporting research integrity

The Australian Code for the Responsible Conduct of Research, 2018 (the Code) requires research to be conducted with the requisite approvals, permits or licences. Below is a list (non-exhaustive) of the laws, regulations, guidelines and other codes of practice that apply to the conduct of research. Researchers are expected to be aware of and comply with the applicable laws and codes.

OVERARCHING RULES & CODES FOR ANU RESEARCHERS

ANU ACADEMIC INTEGRITY RULE 2022

ANU CODE OF CONDUCT

ANU ENTERPRISE AGREEMENT 2022-2026

ANU RESPONSIBLE CONDUCT OF RESEARCH POLICY

AUSTRALIAN CODE FOR THE RESPONSIBLE CONDUCT OF RESEARCH, 2018

NATIONAL PRINCIPLES OF INTELLECTUAL PROPERTY MANAGEMENT FOR PUBLICLY FUNDED RESEARCH

PRIVACY ACT 1988

THERAPEUTIC GOODS ACT 1989

The Therapeutic Goods Act 1989 prohibits the importation or supply of unapproved therapeutic goods for use in humans unless they are exempted. Item 1 of Schedule 5A of the Therapeutic Goods Regulations 1990 and Item 2.1 of Schedule 4 of the Therapeutic Goods (Medical Devices) Regulations 2002 allows for the importation of unapproved products under Sections 18, 19, 41HA, 41HB or 41HC of the Act, but they must be stored and not supplied for use in humans until that approval or notification is finalised.

Importation of a product/s for an unapproved use or as part of a clinical trial may be subject to additional restrictions for which additional and separate approvals may be required under legislation governing:

- the Customs (Prohibited Imports) Regulations 1956 (for example, products containing abortifacients, antibiotics, anabolic steroids, growth hormones, narcotics, psychotropic medicines and certain prohibited substances);
- the Biosecurity (Consequential Amendments and Transitional Provisions) Act 2015(for example, materials of biological origin);
- the Environment Protection and Biodiversity Conservation Act 1999 (for example, products originating from endangered species); and
- current arrangements for the prior approval of clinical investigations involving genetically modified materials.

USE OF CARCINOGENIC OR HIGHLY TOXIC CHEMICALS

Research involving the use of carcinogenic or highly toxic chemicals must adhere to Safe Work Australia's Code of Practice, Preparation of Safety Data Sheets for

Hazardous Chemicals. Further information is available from the Safe Work Australia website.

- the Biosecurity (Consequential Amendments and Transitional Provisions) Act 2015(for example, materials of biological origin);
- the Customs (Prohibited Imports) Regulations 1956 (for example, products containing abortifacients, antibiotics, anabolic steroids, growth hormones, narcotics, psychotropic medicines and certain prohibited substances);
- the Environment Protection and Biodiversity Conservation Act 1999 (for example, products originating from endangered species)

The use of datasets for research purposes must comply with the Minimum Guidelines for Health Registers for Statistical and Research Purposes. Further information is available from the Australian Institute of Health and Welfare website.

RESEARCH INVOLVING ANIMALS

A GUIDE TO THE CARE AND USE OF AUSTRALIAN NATIVE MAMMALS IN RESEARCH AND TEACHING (2014)

AUSTRALIAN CODE FOR THE CARE AND USE OF ANIMALS FOR SCIENTIFIC PURPOSES, 8TH EDITION (2013)

BIOSECURITY (CONSEQUENTIAL AMENDMENTS AND TRANSITIONAL PROVISIONS) ACT 2015

CUSTOMS (PROHIBITED IMPORTS) REGULATIONS 1956

ENVIRONMENT PROTECTION AND BIODIVERSITY CONSERVATION ACT 1999

GUIDELINES TO PROMOTE THE WELLBEING OF ANIMALS USED FOR SCIENTIFIC PURPOSES: THE ASSESSMENT AND ALLEVIATION OF PAIN AND DISTRESS IN RESEARCH ANIMALS (2008)

RESEARCH INVOLVING ANIMALS

Research involving the use of animals must comply with relevant state and territory animal welfare legislation and Commonwealth legislation related to biosecurity and compliance with the Convention on International Trade in Endangered Species of Wild Fauna and Flora. Research involving the use of animals must be reviewed and approved by a properly constituted Animal Ethics Committee as being in accordance with the Australian Code for the Care and Use of Animals for Scientific Purposes 8th edition 2013. See also A Guide to the care and use of Australian native mammals in research and teaching (2014) and Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals (2008).

RESEARCH INVOLVING HUMANS

AUSTRALIA COUNCIL FOR THE ARTS, INDIGENOUS CULTURAL PROTOCOLS FOR PRODUCING INDIGENOUS AUSTRALIAN MUSIC, WRITING, VISUAL ARTS, MEDIA ARTS AND PERFORMING ARTS (2007)

ETHICAL CONDUCT IN RESEARCH WITH ABORIGINAL AND TORRES STRAIT ISLANDER PEOPLES AND COMMUNITIES: GUIDELINES FOR RESEARCHERS AND STAKEHOLDERS (2018)

REGISTRATION OF CLINICAL TRIALS

Clinical trials which are initiated in Australia or New Zealand must be registered with the Australian New Zealand Clinical Trials Registry (ANZCTR), prior to recruitment of patients into the trial. Other NHMRC-funded trials which are part of an existing study or which are being conducted overseas must be registered on ANZCTR or an equivalent clinical trials registry such as the US National Institutes of Health ClinicalTrials.gov or a primary registry on the World Health Organization's International Clinical Trials Registry Platform (ICTRP), prior to the recruitment of patients into the trial.

RESEARCH INVOLVING HUMAN EMBRYOS

Research involving certain human embryos requires a licence issued by the Embryo Research Licensing Committee of NHMRC in accordance with the Research Involving Human Embryos Act 2002 and the Prohibition of Human Cloning for Reproduction Act 2002.

RESEARCH INVOLVING HUMANS

Research involving human participants must be reviewed by a Human Research Ethics Committee (HREC) or through an appropriate ethics review process in accordance with the National Statement on Ethical Conduct in Human Research 2007 (the National Statement). Consideration must also be given to the Privacy Act 1988.

Human research includes interventional research, non-interventional clinical research, other health research, research involving human biospecimens and any other research involving information obtained from human beings.

All research involving the administration of drugs, chemical agents or vaccines to humans or devices in humans must be considered by a HREC to assess the appropriateness of their use. If such research is part of an Australian-based clinical trial, then it may need to be notified to or approved by the Therapeutic Goods Administration (TGA), which administers the Clinical Trials Notification (CTN)/Exemption (CTX) schemes. This does not apply to clinical trials in which registered or listed medicines or medical devices are used within the conditions of their marketing approval. Further information on the CTN/CTX schemes can be obtained from the TGA website.

In the case of multi-centre human research, the relevant institutions and their HRECs may agree that the primary ethical and scientific assessment be made at one institution/organisation, with notification of the approval to the other institutions/organisations involved in the research project. Further information on single ethical review is provided in the National Statement and from jurisdictional health departments.

NAGOYA PROTOCOL ON ACCESS AND BENEFITS-SHARING

NATIONAL STATEMENT ON ETHICAL CONDUCT IN HUMAN RESEARCH (2007)—UPDATED 2018

NATIONAL STATEMENT ON ETHICAL CONDUCT IN HUMAN RESEARCH (2023)—EFFECTIVE 1 JANUARY 2024

USE OF DATASETS FOR RESEARCH PURPOSES

RESEARCH INVOLVING RECOMBINANT DNA

BIOSECURITY (CONSEQUENTIAL AMENDMENTS AND TRANSITIONAL PROVISIONS) ACT 2015

CUSTOMS (PROHIBITED IMPORTS) REGULATIONS 1956

DEFENCE TRADE CONTROLS ACT 2012

NAGOYA PROTOCOL ON ACCESS AND BENEFITS-SHARING

Australia has been a signatory to Nagoya Protocol since 2012. The protocol will establish a legally-binding framework for biotechnology researchers and other scientists to gain access to genetic resources located outside Australia. It also establishes a framework for researchers and developers to share any benefits from the use of genetic resources, or traditional knowledge associated with those resources, with the provider country. More information can be obtained from the Australian Government Department of Environment and Energy website and from the Nagoya Protocol Access and Benefit-sharing Clearing-house (ABSCH).

RESEARCH INVOLVING GENETICALLY MODIFIED ORGANISMS

Research involving genetically modified organisms (GMO) must comply with all the requirements of the Gene Technology Act 2000 and Gene Technology Regulations 2001.

Information on the gene technology regulatory scheme, including the Act and Regulations, is also available from the Office of the Gene Technology Regulator website.

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RESEARCH INVOLVING INTERNATIONAL COLLABORATIONS

BIOSECURITY (CONSEQUENTIAL AMENDMENTS AND TRANSITIONAL PROVISIONS) ACT 2015

CUSTOMS (PROHIBITED IMPORTS) REGULATIONS 1956

DEFENCE TRADE CONTROLS ACT 2012

Requirements relating to the supply of controlled technology ('dual-use') and the dissemination of intangible technology articulated in the Defence Trade Controls Act 2012, including by way of publication or presentation. More information on the requirements of the legislation can be obtained from the Defence Trade Controls Act 2012, and from the Defence Export Controls (DEC) website.

FOREIGN ARRANGEMENTS SCHEME

FOREIGN INTERFERENCE ADVISORY COMMITTEE

NAGOYA PROTOCOL ON ACCESS AND BENEFITS-SHARING

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resources, with the provider country. More information can be obtained from the Australian Government Department of Environment and Energy website and from the Nagoya Protocol Access and Benefit-sharing Clearing-house (ABSCH).

IMPORTS AND EXPORTS OF TANGIBLE AND/OR INTANGIBLE MATERIALS

BIOSECURITY (CONSEQUENTIAL AMENDMENTS AND TRANSITIONAL PROVISIONS) ACT 2015

CUSTOMS (PROHIBITED IMPORTS) REGULATIONS 1956

DEFENCE TRADE CONTROLS ACT 2012

Requirements relating to the supply of controlled technology ('dual-use') and the dissemination of intangible technology articulated in the Defence Trade Controls Act 2012, including by way of publication or presentation. More information on the requirements of the legislation can be obtained from the Defence Trade Controls Act 2012, and from the Defence Export Controls (DEC) website.

ENVIRONMENT PROTECTION AND BIODIVERSITY CONSERVATION ACT 1999

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FUNDING AGENCY POLICIES

ARC RESEARCH INTEGRITY POLICY

NATIONAL INSTITUTES OF HEALTH (USA) RESEARCH INTEGRITY

ANU researchers who receive funding from the NIH need to be aware of the requirements of the Public Health Service (PHS) policies on research misconduct.

NHMRC RESEARCH INTEGRITY AND MISCONDUCT POLICY

Guidelines approved under Section 95 of the Privacy Act 1988 (s95 guidelines) or the Guidelines approved under Section 95A of the Privacy Act 1988 (s95A guidelines).