



## Research Ethics Policy

Document Area	Academic Quality Assurance and Enhancement
Document Function/ Owner	Vice President for Research and Innovation
Author(s)	Research Ethics Working Group Quality Assurance and Enhancement Team (qaet@atu.ie)
Required Approval	Academic Council

### Issued Document Location

Internal Staff Portal / Hub	Yes (default repository)
Internal Student Portal / Hub	Yes
ATU Website	Yes
Issue Date	26 April 2024
Effective Date	01 September 2024

## Table of Contents

<b>1.</b>	<b>Purpose.....</b>	<b>4</b>
<b>2.</b>	<b>Scope .....</b>	<b>4</b>
<b>3.</b>	<b>External Reference Documents.....</b>	<b>5</b>
<b>4.</b>	<b>Policy .....</b>	<b>6</b>
4.1	Definitions .....	6
4.2	Ethical Principles .....	9
4.3	Ethical approval process.....	10
4.3.1	Externally approved research ethics applications .....	13
4.3.2	Taught post-graduate and undergraduate research. ....	13
4.3.3	Applied Learning Projects .....	14
4.4	Research involving Human Participants .....	14
4.4.1	Informed consent.....	14
4.4.2	Privacy, confidentiality, and anonymity .....	15
4.4.3	Data Management and Data Protection.....	15
4.4.4	Dissemination .....	15
4.4.5	Vulnerable research participants.....	15
4.4.6	ATU students as research participants .....	16
4.4.7	Equality, Diversity, and Inclusion .....	16
4.5	Research of a Clinical Nature .....	16
4.6	Other Research Activities .....	17
4.6.1	International research .....	17
4.6.2	Dual-Use Research and Export Controls .....	17
4.7	Responsibilities.....	18
4.7.1	Researchers.....	18
4.7.2	Faculty Research Ethics Committees (FRECs) .....	19
4.7.3	University Research Ethics Committee (UREC).....	20
4.7.4	VP for Research and Innovation .....	20
4.7.5	Research Office .....	21
4.7.6	Academic Council.....	21
<b>5.</b>	<b>Associated Documents Related to this Policy .....</b>	<b>21</b>

**6. Revision History ..... 21**

**Appendix 1 ATU Research Ethics Approval Process..... 22**

## 1. Purpose

Atlantic Technological University (ATU) endeavours to ensure that all research carried out by its research community is ethically sound and adheres to the highest standards of research integrity. We recognise that research must always be designed and conducted in accordance with ethical principles, and that appropriate review processes are in place to ensure adherence to those principles.

This policy articulates the guiding principles for ethical research that ATU commits to. These principles are informed by international ethical guidelines, relevant EU directives, national legislation and guidelines, and statements of appropriate ethical practice set out by relevant professional bodies. This policy also provides an overview of the review and approval mechanisms established by ATU and its requirements for applying for ethical approval.

## 2. Scope

This policy applies to all those engaged in research within, and under the auspices of ATU, which includes:

- all ATU staff (including contract research staff) carrying out research on any of the ATU campuses, or on behalf of the ATU at another location,
- all registered students and their supervisors (internal and external to ATU) undertaking a research project at an ATU campus or another location, and
- any individuals carrying out any research under the auspices of ATU with external collaborators.

The term “researchers” is used as an all-encompassing term in this policy, inclusive of all those listed above. Where there are specific additional requirements for research students and their supervisors’, these are specified.

Researchers are expected to comply with this policy, and specific legislation, regulations, ethical standards, and professional codes of conduct as relevant to their research field.

Compliance with this policy is required irrespective of whether research ethics approval has been approved by another Higher Education Institution (HEI) or Research Ethics Committee (REC).

This policy relates to the ethical conduct of research activities within ATU to ensure adherence to established principles of integrity, honesty, and ethical behaviour in all aspects of research endeavours.

While this policy addresses research-specific ethical considerations, it also recognises that matters pertaining to honesty and integrity, including but not limited to plagiarism, fabrication of results, and falsification of data, are key to the integrity of research and to

creating a research culture that is built on the principles of research integrity and research ethics.

Principles of research integrity are also addressed in the University's *Academic Integrity Policy (AQAE022)* and in the University's *Student Code*. This policy underscores the significance of integrity within the research context, while matters concerning integrity violations are appropriately deferred to and managed under the purview of the *Academic Integrity Policy* and its related procedures.

In compliance with statutory obligations, research involving the use of live animals is governed by the University's *Policy for Use of Animals for Research & Teaching (AQAE025)*. The Animal Research Ethics Committee (AREC) established by that policy, considers all research proposals that involve the use of animals.

### 3. External Reference Documents

The following documents have been consulted in the development of this policy:

- Academic Integrity Guidelines (National Academic Integrity Network, 2021)
- Common Military List of the European Union (Official Journal of the European Union, 2020)
- Control of Exports Act, 2023
- Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects (The World Medical Association (WMA), 2013)
- Declaration of Taipei on Ethical considerations regarding health databases and biobanks (WMA, 2016)
- Impact 2030: Ireland's Research and Innovation Strategy (Department of Further and Higher Education, Research, Innovation and Science, 2022)
- EU Control List of Dual-use Items (Official Journal of the European Union, 2023)
- National Action Plan for Open Research, 2022-2030 (National Open Research Forum (NORF), 2022)
- National Vetting Bureau (Children and Vulnerable Persons) Acts 2012 to 2016
- Policy Statement on Ensuring Research Integrity in Ireland (Research Integrity National Forum, 2019)
- Principles of Good Practice in Research in Irish Higher Education Institutions (HEA, 2019)
- The European Code of Conduct for Research Integrity (All European Academies (allea), 2023)
- The TRUST Code: A Global Code of Conduct for Equitable Research Partnerships (adopted by the European Commission, 2018)
- Universal Declaration on Bioethics and Human Rights (UNESCO, 2005)

## 4. Policy

### 4.1 Definitions

#### 4.1.1 Conflict of Interest

A 'conflict of interest' be it actual, potential, or perceived, arises when an individual holds a personal interest, whether direct or indirect, which in the opinion of a reasonably informed and well-advised person is sufficient to call into question the independence, impartiality, and objectivity the individual is obliged to exercise in the performance of his/her duties. The *ATU Conflict of Interest Policy and Procedure* should be consulted for further details on conflicts of interests.

#### 4.1.2 Consent and Assent

Consent refers to the informed and explicit agreement of a prospective research participant to take part in a research study and, when relevant, to the use of their personal data for such research.

Assent is the expressed agreement of someone not able to give legal consent such a vulnerable adult or child.

#### 4.1.3 Data Minimisation

Data minimisation is a research ethics principle, which applies particularly to research involving human participants and requires the researcher to limit the collection of personal information to what is directly relevant and necessary to accomplish the specified research objectives.

#### 4.1.4 Data Protection

Data Protection refers to protecting the rights of research participants by implementing measures to protect their personal data. All researchers must comply with the *ATU Data Protection Policy*. ATU is committed to complying with all applicable data protection, privacy and security laws and regulations and with protecting the rights and freedoms of individuals with respect to the processing of their personal data.

#### 4.1.5 Dual-use research

Dual-use research is research that is used to produce new knowledge that could easily be misused in harmful ways. Dual-use items cover both technology and software and can include items that could be used for the design, development, production, or use of nuclear, chemical, or biological weapons or their means of delivery, as well as technologies that can monitor individuals or be used in surveillance.

#### 4.1.6 Export Control

Export Control is a multi-lateral, global mechanism designed to prevent the proliferation of weapons of mass destruction, to preserve regional stability, to prevent terrorism and to protect human rights. The *Control of Exports Act 2023* obliges exporters to obtain prior authorisation i.e., an Export Licence, for the export of items listed on their technical lists, or any technology, technical assistance, software, or knowhow relating to those items, to a third country. A third country is a country that is not a member of the European Union as well as a country or territory whose citizens do not enjoy the European Union right to free movement.

#### 4.1.7 National Research Ethics Committees (NREC)

The National Office for Research Ethics Committees is an independent office with a statutory function. It has established NRECs in specific areas of health research.

#### 4.1.8 Open Access

Open Access refers to online, free of cost access to peer reviewed research content with limited copyright and licensing restrictions.

#### 4.1.9 Open Science

Open Science is defined as an inclusive construct that combines various movements and practices aiming to make multilingual scientific knowledge openly available, accessible, and reusable for everyone, to increase scientific collaborations and the sharing of information for the benefits of science and society, and to open the processes of scientific knowledge creation, evaluation, and communication to societal actors beyond the traditional scientific community.

#### 4.1.10 Research Data Management

Research Data Management (RDM) is the term used to describe what data is collected by a researcher, and how it is collected, stored, preserved, shared, and destroyed. Researchers must have a plan for how to address RDM in their research proposal. This must comply with the *ATU Data Protection Policy*. The principles of research integrity and good research practice must also be taken into consideration when sharing, publishing, disseminating, identifying authorship and in the destruction of data.

#### 4.1.11 Research Integrity

Research integrity relates to the performance of research to the highest standards of professionalism and rigour, and to the accuracy and trustworthiness of the research record in publications and elsewhere.

#### 4.1.12 Research Misconduct

Research misconduct refers to violations of good research practice that distort the research record or damage the integrity of the research process or of researchers.

Fabrication, falsification, or plagiarism, commonly referred to as FFP categorisation are serious incidences of research misconduct.

- Fabrication is making up results and recording them as if they were real.
- Falsification is manipulating research materials, equipment or processes or changing, omitting, or suppressing data or results without justification.
- Plagiarism is using other people's work and ideas without giving proper credit to the original source, thus violating the rights of the original author(s) to their intellectual outputs.

#### 4.1.13 Risk

Risk is the potential for harm in terms of magnitude, probability, and permanency. Minimal risk generally refers to situations where the magnitude and probability of harm is not greater than that experienced in everyday life.

#### 4.1.14 Vulnerable person

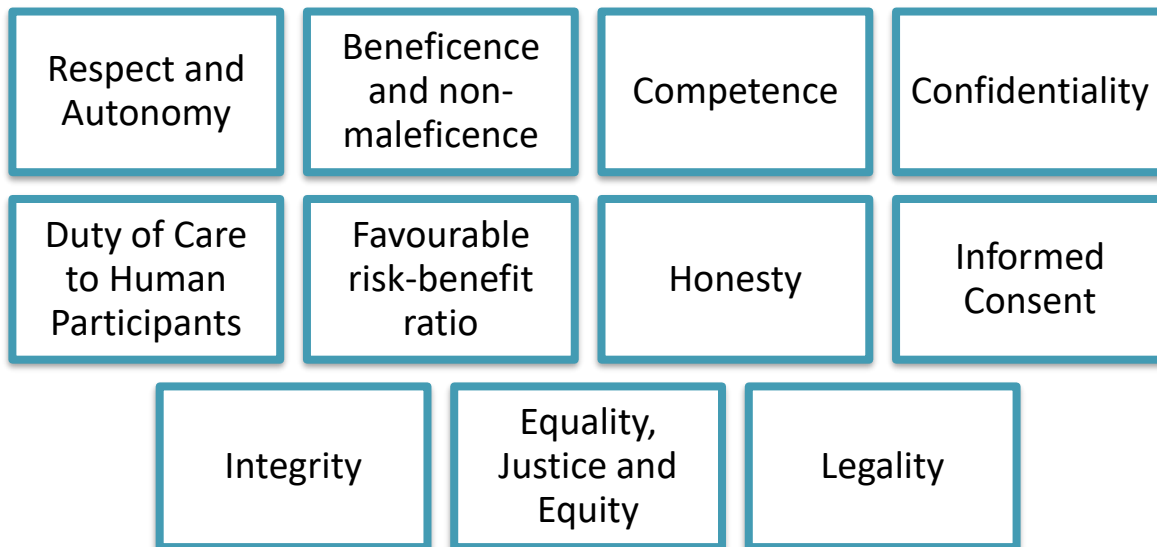
A vulnerable person is defined in the National Vetting Bureau (Children and Vulnerable Persons) Acts 2012 to 2016 as a person, other than a child, who:

- a. is suffering from a disorder of the mind, whether as a result of mental illness or dementia,
- b. has an intellectual disability,
- c. is suffering from a physical impairment, whether as a result of injury, illness, or age, or
- d. has a physical disability, which is of such a nature or degree:
  - i. as to restrict the capacity of the person to guard himself or herself against harm by another person, or
  - ii. that results in the person requiring assistance with the activities of daily living including dressing, eating, walking, washing, and bathing.



## 4.2 Ethical Principles

ATU requires that all researchers carry out research to the highest ethical standards of excellence underpinned by the principles outlined in Figure 1.



**Figure 1** Ethical principles underpinning research at ATU.

**Respect and autonomy:** commitment to respect the self-determination of adults who have decision-making capacity.

**Beneficence and non-maleficence:** commitment to uphold the moral obligation to do good, maximise the benefit (beneficence) of research and the moral obligation to do no harm (non-maleficence).

**Competence of the researcher:** the expectation that researchers will have the required education, competence, and professional skill necessary to undertake the research. Students engaging in research at ATU must be competently and adequately supported to attain competence in their research activities.

**Confidentiality:** commitment to preserving participant privacy while data is collected, managed, retained, and destroyed with confidentiality.

**Duty of Care to Human Participants:** when conducting research with human participants it is expected that the principle of minimising risks and maximising the research benefits will be demonstrated. This requires that researchers:

- respect the autonomy, dignity, privacy, rights, safety, and wellbeing of all actual or potential human research participant(s),
- apply special precautions when dealing with minors and vulnerable individuals,
- limit errors in the design and conduct of research,

- not be negligent in the design and conduct of their research, and
- maintain records securely and confidentially.

**Favourable risk–benefit ratio** recognises that research is ethical if the potential risks to participants are minimised, the potential benefits to participants are enhanced, and the potential benefits to participants and society are proportionate to or outweigh the risks.

The requirement for a favourable risk–benefit ratio embodies the principles of non-maleficence and beneficence.

**Honesty:** commitment to honesty in all our research activities. We expect truthfulness and transparency and strive to create an environment where integrity and ethical conduct are valued and upheld.

**Informed consent:** is a mutually negotiated process which results in a person voluntarily opting into a research study as a participant or data subject. Informed consent must only be obtained after the potential participant has been fully informed of what the research study will entail, what they will be required to do as a participant, and what will happen to their data.

**Integrity (Academic/Research):** commitment to compliance with ethical and professional principles, standards and practices and consistent system of values, that serves as guidance for making decisions and taking actions in education, research, and scholarship.

**Equality, Justice, and Equity:** the university respects the fundamental equality of all human beings. We commit to treating all justly and equitably, respecting their dignity and rights. This commitment is fundamental to our approach to fairness in the recruitment and treatment of research participants.

**Legality:** the expectation of knowledge of and compliance with EU, and national legal requirements and ATU requirements.

### 4.3 Ethical approval process

The university requires that all research activities, whether externally funded or not, undergo an ethical review and approval process. This is a self-declaration process that requires researchers to ensure their proposed research has been approved before commencement of the work. Research ethics approval will not be considered retrospectively.

The university requires that all research projects are designed in adherence with the ethical principles articulated in this policy and the duty of researchers to abide by these ethical principles must be the fundamental concern when deliberating on the ethical issues related to a particular project.

ATU establishes the following RECs to adjudicate on research ethics applications:

- University Research Ethics Committee (UREC)
- Faculty Research Ethics Committees (FRECs)
- Animal Research Ethics Committee (AREC)

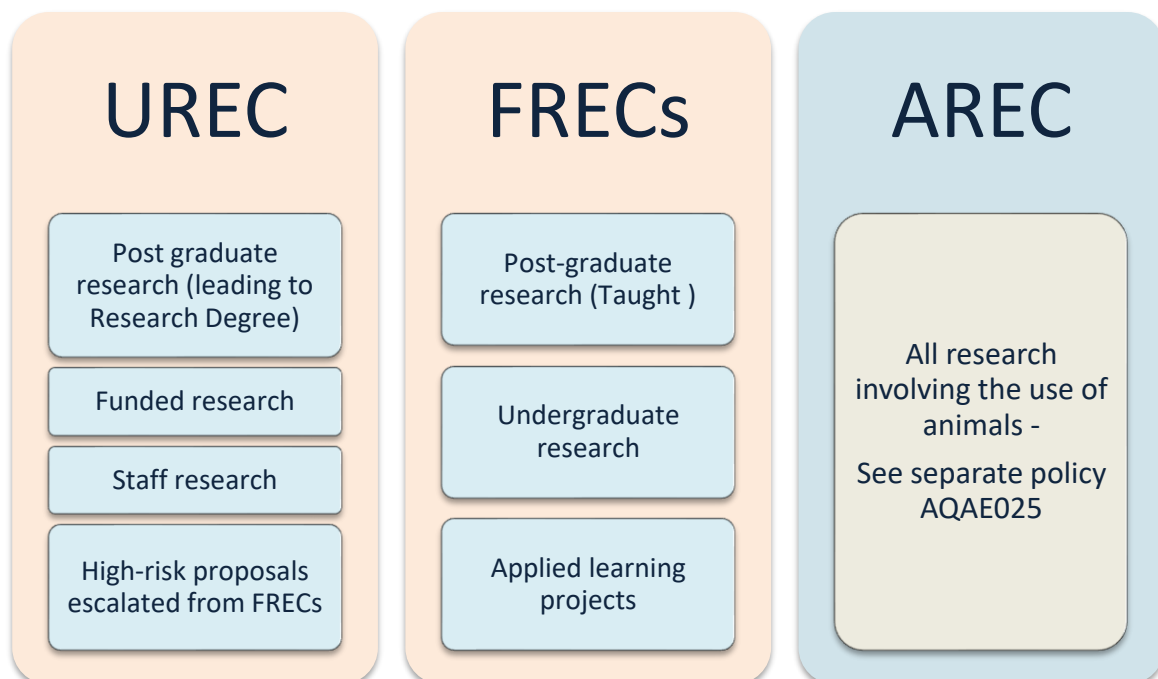
Taught postgraduate research and undergraduate research applications must be submitted to the relevant FREC.

Research leading to a research degree (as defined in the *Research Degree Policy (AQAE011)*), funded research, and staff research applications must be submitted to the UREC.

The approval process is detailed in *Procedure for Applying for Research Ethics Approval (AQAEXXX)*. Appendix 1 provides an overview of the approval process.

The AREC is established in accordance with the *Use of Animals for Research & Teaching Policy (AQAE025)*. All research proposals involving the use of animals must submit applications to the AREC.

Figure 2 illustrates the type of research considered by ATU RECs.



**Figure 2** Research Ethics Committees established at ATU and their remit.

The University requires all researchers to complete the *ATU Ethics Self-Assessment Checklist Form*.

Completion of the *ATU Ethics Self-Assessment Checklist Form* will aid researchers to adjudicate on their research proposal from a research ethics perspective. The assessment requires researchers to indicate whether no further action is required or whether the proposal must be reviewed and approved by a REC.

Research supervisor(s) or lecturer(s), (in the case of taught programmes) are required to sign-off on all student *ATU Ethics Self-Assessment Checklist Forms* before they are submitted to the REC.

All researchers must submit their *ATU Ethics Self-Assessment Checklist Form* to the appropriate REC for:

- approval (where no further action is required), or
- ethical review and approval by the REC.

Where ethical review and approval is indicated during the self-assessment process the following documentation must be submitted along with the *ATU Ethics Self-Assessment Checklist Form*:

- *ATU Ethical Approval Application Form*
- *Participant Information Sheet* and *Informed Consent Form* (templates provided), and any other relevant supporting documentation, as required.

The *ATU Ethical Approval Application Forms* and all supporting documentation must be signed-off by the research supervisor(s), or lecturer(s), (in the case of taught programmes) for student applications.

Risks associated with all research conducted in, and under the auspices of ATU must be identified and evaluated in the design of the project and monitored throughout the lifespan of the project.

The *ATU Ethics Self-Assessment Checklist Form* should aid in identifying if a more detailed risk evaluation, which describes the magnitude, level of risk and the probability of occurrence, must be conducted by the researchers.

In general, risk level is evaluated by considering:

1. The nature of the research
2. Participants involved in the Research (where applicable)
3. Data collection and nature of the data to be collected.

Researchers must be able to determine the specific risks associated with the work they are planning to conduct. Research students must consult with their supervisor(s)/lecturer(s) to conduct an informed risk evaluation.

The UREC holds a critical role in safeguarding ethical standards in research at ATU and is the ultimate authority in evaluating and approving research ethics applications.

The UREC devolves this decision-making to the FRECs for research proposals for taught post-graduate and undergraduate research. However, applications that are deemed high risk may be escalated by a FREC to the UREC for adjudication. Decisions made by the RECs are final.

RECs may decide to (1) approve, (2) approve, subject to minor amendment, (3) require a resubmission, or (4) reject a research ethics application.

The REC may advise on risk reduction or mitigation measures that should be taken into consideration when revising and resubmitting a research proposal for ethics approval.

Applicants have the right to appeal a decision. An appeal of a FREC decision may be considered by the UREC in exceptional circumstances. An appeal of a UREC decision must be considered by an appeals committee, constituted by the VP for Research and Innovation. The appeals committee must comprise members from appropriate external ethics committees who are experienced researchers in the relevant discipline.

The appeal process is detailed in the *Procedure for Appealing the Decision of a Research Ethics Committee (AQAEXXX)*.

#### 4.3.1 Externally approved research ethics applications

Research proposals that have been reviewed and approved by another REC external to ATU must be submitted to the UREC for consideration. The *ATU Ethics Self-Assessment Checklist* must be submitted, accompanied with all correspondence associated with the approval from the external REC. The application may not require a full ethical review, but the UREC must satisfy itself that a rigorous ethical review process has been conducted.

#### 4.3.2 Taught post-graduate and undergraduate research.

FRECs must provide guidance on evaluating risk. This must be underpinned by discipline best practice and norms, precedence based on previous ethics applications and where appropriate, professional body regulations and best practice. All FREC research ethics guidelines must be approved by the UREC.

Undergraduate students and taught post-graduate students at ATU that undertake a research project must also complete a risk evaluation.

### 4.3.3 Applied Learning Projects

Applied learning and industry engagement is encouraged throughout the teaching, learning and assessment practices at the ATU. Many small-scale projects/ activities incorporated in taught programmes at ATU involve applied learning or engagement with industry. All lecturers must consider whether their applied learning activity requires ethical approval.

## 4.4 Research involving Human Participants

All research involving human participants must ensure the safeguarding and welfare of these participants. Special consideration must be given to protecting the welfare of any vulnerable research participants.

### 4.4.1 Informed consent

All research participants must be supplied with a *Participant Information Sheet* and *Informed Consent Form*. This documentation must clearly explain why their participation is requested, the benefits and the risks of the research to them, how the research will be used, how the data will be stored and protected and how and to whom the outputs/outcomes will be reported.

Participants must be informed of all risks associated with their participation. Risks must be clearly articulated in language that is accessible to a lay person on the *Participant Information Sheet* to ensure fully informed consent. Expressed consent from the potential participant for each identified risk must be clearly documented on the *Informed Consent Form*.

Researchers must ensure that informed consent is secured from all research participants. This can be obtained in writing or electronically (e.g. via a check box). Obtaining consent from potential research participants must adhere to the following criteria:

1. Comprehensive and clear information using a *Participant Information Sheet*, written in accessible language suitable for a lay person, must be provided.
2. Consent must be given on a voluntarily basis, without coercion or deceit, or undue influence through incentives.
3. The opportunity to refuse to participate, with a clear understanding that a decision not to participate will have no negative outcomes, must be communicated.
4. Potential participants must be advised of their right to withdraw from the research on both the *Participant Information Sheet* and the *Informed Consent Form*. This must include information regarding the different time points of withdrawal of data, when withdrawal is possible, how to withdraw, timeframe in which withdrawal is possible and the rationale for this timeframe.
5. Information must be provided on the timeframe for retention of data on both the *Participant Information Sheet* and the *Informed Consent Form*.
6. Information about the research topic, prior to giving consent, must be provided.

7. The individual must have the capacity to consent or consent on behalf of children and vulnerable adults by their parent/guardian must be given as informed consent.
8. Vulnerable persons and children must be provided with an appropriate explanation of the research and researchers should obtain their assent to participate, in addition to the appropriate consent provided by their parent/guardian.

Researchers working with children and vulnerable persons must be vetted before the research commences, in accordance with the *National Vetting Bureau (Children and Vulnerable Persons) Acts 2012 to 2016* and the relevant University policies and procedures.

Researchers must also be informed of and comply with the *ATU Child Protection Policy*.

#### 4.4.2 Privacy, confidentiality, and anonymity

Privacy, confidentiality, and anonymity of participants must be maintained where possible. This applies to the identity of the participant, through both direct or indirect identifiers, and the protection of participant data. The principle of data minimisation must also be upheld i.e. do not collect any more data than is necessary or required for the research.

#### 4.4.3 Data Management and Data Protection

The collection, storage, and use of data of a sensitive or confidential nature requires careful consideration and must be dealt with in an ethical manner and reflected in the informed consent process.

The *ATU Data Protection Policy* articulates a common core set of values, principles and procedures intended to achieve a standard set of universal compliance parameters based on General Data Protection Regulations (GDPR) and Data Protection Act 2018. The ATU Data Protection Policy must be consulted by researchers alongside this policy when completing their ethics application. All research conducted at ATU must comply with GDPR.

#### 4.4.4 Dissemination

Arrangements for the dissemination and publication of the results, must be conducted in an ethical manner and in adherence with the arrangements articulated and agreed to on the *Informed Consent Form*.

#### 4.4.5 Vulnerable research participants

Vulnerable research participants are individuals who are at risk of vulnerability. This includes, but is not limited to:

- persons who may require support to give consent, such as children (<18 years of age) and vulnerable persons,
- patients of the healthcare system,

- persons from low-income countries, political instable or countries at conflict, or persons seeking asylum,
- prisoners,
- persons living in socio-economic circumstances that may make them vulnerable to exploitation, and
- participants who have an unequal power relationship with the researcher e.g. student/lecturer, employee/manager.

Researchers must carefully consider and demonstrate how the potential and actual benefits of the research outweigh the possible harm to participants when conducting research with vulnerable participants.

#### 4.4.6 ATU students as research participants

Ethics approval is required to recruit ATU students as research participants. In addition, researchers should also seek permission from the relevant Head(s) of Faculty.

#### 4.4.7 Equality, Diversity, and Inclusion

ATU is committed to being a diverse, equal, and inclusive university and is making progress on embedding equality, diversity, and inclusion (EDI) principles across everything we do. Researchers must ensure that EDI best practices are incorporated into their research.

### 4.5 Research of a Clinical Nature

Research of a clinical nature is regarded as high-risk by the University and includes, but is not limited to:

1. Therapeutic interaction with human participant(s).
2. A clinical trial of, for example, a medical device, medicinal product, or clinical technique
3. The development of diagnostic techniques involving human participants
4. Access to, or utilisation of, human remains, cadavers, tissues, discarded tissue (e.g. placenta), and biological fluids.
5. Access to, or utilisation of, identifiable medical data concerning individuals (such as clinical data records) by parties not directly concerned in the provision of care to these individuals.
6. Interaction with and/or observation of individuals in a healthcare context or setting.
7. Evaluation of patient experience outside the healthcare setting.
8. Use of known teratogens, carcinogens, and any cytotoxic substances in clinical trials.
9. Use of harmful substances in human participants or animal participants.
10. Use of ionising radiation with human participants.

Other research that may be regarded as clinical in nature must be declared high-risk for the purpose of ethics approval.



## 4.6 Other Research Activities

The following research activities must be explicitly declared, and detail provided in a research ethics application:

- Any potential conflict of interest, particularly due to financial incentives and/or benefits from a sponsor,
- Where ethical approval is a stated requirement of the funding agency,
- Research involving the use of health databases and biobanks,
- Research involving genetic manipulation or Genetically Modified Organisms (GMOs),
- Research involving the use of Artificial Intelligence, and
- Emerging areas of research or any research where the researcher is uncertain of the requirement.

### 4.6.1 International research

Research that is to be undertaken outside of the country requires the researcher to:

- Comply with legislative and ethical approval requirements of the host country,
- ensure compliance with GDPR,
- recognise and mitigate against the potential for power-imbalance that arises when research is conducted in for example low-income countries or countries experiencing conflict or political instability,
- demonstrate sensitivity to differences in cultural, moral, and political opinion and local customs, and
- abide by the TRUST Code: A Global Code of Conduct for Equitable Research Partnerships.

### 4.6.2 Dual-Use Research and Export Controls

Researchers must be aware of the legislative requirements governing export controls and how this relates to dual-use research. Researchers will find more detail in the universities *Export Controls Policy (under development)*.

The term 'export' covers a broad range of essential University activities, including, but not limited to:

- speaking at a conference, meeting, or seminar outside the EU,
- collaborating with international researchers on research projects,
- overseas researchers who visit ATU and then take technology/knowhow home with them,
- teaching outside the EU in areas relating to dual-use items,
- exporting prototypes, second-hand lab equipment etc.,
- sending information electronically via email or shared servers,
- participating in tele or video meetings, and

- academic publications.

There are certain exemptions for basic scientific research and for material that is already in the public domain, but these are interpreted very narrowly and need to be considered carefully on a case-by-case basis as to whether they might apply.

Export Controls Awareness Training will be provided for post-graduate research students and staff, and the Research Office will provide information and support to comply with university policy and export control legislation.

Researchers must highlight dual-use issues in their risk evaluation of a project, providing sufficient detail to allow the REC to adjudicate on the risk.

Researchers must ensure and indicate they have considered whether their research requires an Export Control Licence. The Military Items List and the Dual-Use Item list are technical lists published and updated under national and EU legislation and must be consulted in this regard. Items on the military list need an export licence to leave Ireland. Items on the Dual-Use list need an export licence to leave the EU.

In instances where an Export Control License is required, it must be addressed in the ethical approval process. If Export Controls do not apply, it must be declared.

The Research Office provides support for applications for Export Control Licenses in accordance with its *Export Controls Policy (under development)*.

## **4.7 Responsibilities**

### **4.7.1 Researchers**

It is important that when ATU Researchers engage in research practices, that they do not engage in any activity that causes ATU to come into disrepute.

It is the responsibility of all researchers (including Principal Investigators, Staff, Postgraduate Research Students, Taught Postgraduate Students and Undergraduate Students) to ensure that their research is carried out in an ethical manner throughout the lifecycle of their research studies, from idea to dissemination, with ethical principles articulated in this policy applied at all times.

Researchers must:

- design and conduct their research activities in adherence with the ethical principles articulated in this policy,
- comply with this policy and related university policies including, but not limited to those relating to vetting, data protection, conflict of interest and academic and research integrity,

- seek ethical approval from the appropriate REC, using the relevant ethical approval application forms,
- ensure that ethical approval has been granted prior to conducting any recruitment of participants or data collection (ethical approval cannot be granted after recruitment or data collection has taken place),
- seek approval from the relevant REC for any changes to a research study before proceeding with the research,
- identify gaps in their training and ensure that adequate competencies are acquired before conducting a research activity, and
- complete training provided by the ATU, as and when required.

Furthermore, research students must consult with their supervisors or lecturer(s), (in the case of taught programmes) in relation to research ethics approval, and supervisors or lecturer(s), (in the case of taught programmes) must sign-off on all research ethics approval forms before submission to a REC. Supervisors must also oversee the conduct of student research.

#### 4.7.2 Faculty Research Ethics Committees (FRECs)

Each Faculty must establish a Faculty REC, that will be chaired by the Head of Faculty, or their nominee. The FREC is responsible for:

- reviewing and adjudicating on research ethics applications for taught post-graduate research and undergraduate research proposals,
- communicating decisions to applicants,
- developing guidance documents for taught post-graduate and undergraduate research,
- escalating high-risk or proposals that raise concerns to the UREC,
- keeping and maintaining records of research ethics applications, committee deliberations and decisions, and
- providing a summary report of their activities to the UREC at the end of each academic year.

Each FREC will comprise a minimum of the following:

- Head of Faculty (Chair) or nominee,
- member of the Faculty Office nominated by the Head of Faculty (administrative support),
- one research active member of academic staff from each Department,
- one research active staff member from outside the faculty, and
- a postgraduate research student.

The FREC may establish sub-committees at School/Departmental level. The FREC may co-opt members with particular expertise to aid in its work. These may be internal or external to ATU.

#### 4.7.3 University Research Ethics Committee (UREC)

The University will establish a UREC, that will be chaired by the Vice-President for Research and Innovation.

The UREC will be responsible for:

- reviewing and adjudicating research ethics applications for research leading to a research degree, funded research, and staff research,
- communicating decisions to applicants,
- reviewing and approving research ethics guidelines for FRECs,
- reviewing and adjudicating on high-risk or proposals that raise concerns that are escalated to them by a FREC,
- seeking advice on high-risk proposals in specific areas of health research from the appropriate NREC,
- keeping and maintaining records of research ethics applications, committee deliberations and decisions,
- conducting an appeal to a FREC decision, when required, and
- reporting to the Research and Innovation Committee of Academic Council at the end of each academic year with a summary their activities.

The UREC will comprise a minimum of the following:

- VP for Research and Innovation (Chairperson),
- Chair of the Research and Innovation Committee of Academic Council or their deputy chair (vice-chairperson),
- member of the Research Office nominated by the VP for Research and Innovation (administrative support),
- two research active members of academic staff from each Faculty, and
- the Chair of each FREC, or their nominee from the membership of FREC.

The membership of UREC will be in-situ for a 3-year term. The UREC may co-opt members with particular expertise to aid in its work. These may be internal or external to ATU.

#### 4.7.4 VP for Research and Innovation

The Vice President for Research & Innovation is responsible for

- implementing and managing this policy and associated procedures,
- co-ordinating the UREC, and
- constituting an appeals committee, when required.

#### 4.7.5 Research Office

The Research Office will:

- provide support to applicants in making a research ethics application, and
- organise and promote training in matters of academic and research integrity and research ethics to post-graduate research staff and students.

#### 4.7.6 Academic Council

The Research and Innovation Committee of Academic Council will:

- review and oversee the implementation of this policy,
- review reports from the UREC and make recommendations on changes to policy to the Academic Council, and changes to procedures to the relevant function, and
- promote the provision of training in academic and research integrity and research ethics for supervisors and students.

### 5. Associated Documents Related to this Policy

- *AQAEXXX Procedure for Applying for Research Ethics Approval* (under development)
- *AQAEXXX Procedure for Appealing the Decision of a Research Ethics Committee* (under development)
- *ATU Ethics Self-Assessment Checklist Form* (under development)
- *ATU Ethical Approval Application Form* (under development)
- *Participant Information Sheet template* (under development)
- *Informed Consent Form template* (under development)

### 6. Revision History

Revision No	Description of Change	Approval Date
000	New Policy approved by Academic Council	19/04/2024

## Appendix 1 ATU Research Ethics Approval Process

