TUS
Technological University of the Shannon:
Midlands Midwest
Ollscoil Teicneolaíochta na Sionainne:
Lár Tíre Iarthar Láir

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TUS Ethics Policy for Researchers 2025 - 2028

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Contents

1.0 Introduction

This research Ethics Policy document sets out the procedure and expectations for the conduct of academic research by Technological University of the Shannon: Midlands Midwest (hereafter referred to as TUS) research postgraduate students, TUS staff or external researchers accessing TUS students and/or staff. This research ethics policy relates to the requirements governing research at TUS and adheres to appropriate TUS ethical values and principles. A full copy of the Terms of Reference under which the Research Ethics Committee operates can be found in Appendix 1.

Who does research ethics apply to?		
Who	**Preliminary Approval**	**Full Ethical Approval**
All Research Postgraduates	Form RE 1	Form RE 2 (in identified cases)
TUS Staff (conducting research on TUS staff and/or students) OR TUS Staff conducting independent research which does not have ethical approval from elsewhere and who wish to obtain approval from an ethics committee.	Not required	Form RE 2
External Researchers (conducting research on TUS staff and/or students)	Not Required	Form RE 2

This policy does not prohibit Researchers from applying for research grants or undertaking secondary research / literary reviews however ethical approval is required to commence experimental work or primary research (surveys/reviews etc.).

Approval for such research activity should be sought **prior** to its commencement as **ethical approval cannot be given retrospectively by TUS's Research Ethics Committee.** Failure to comply with the TUS Ethics Policy for Researchers will result in TUS Research Integrity policy being enforced.

2.0 Ethics for Researchers

An overview of the governance of ethics at TUS is outlined in Figure 1.

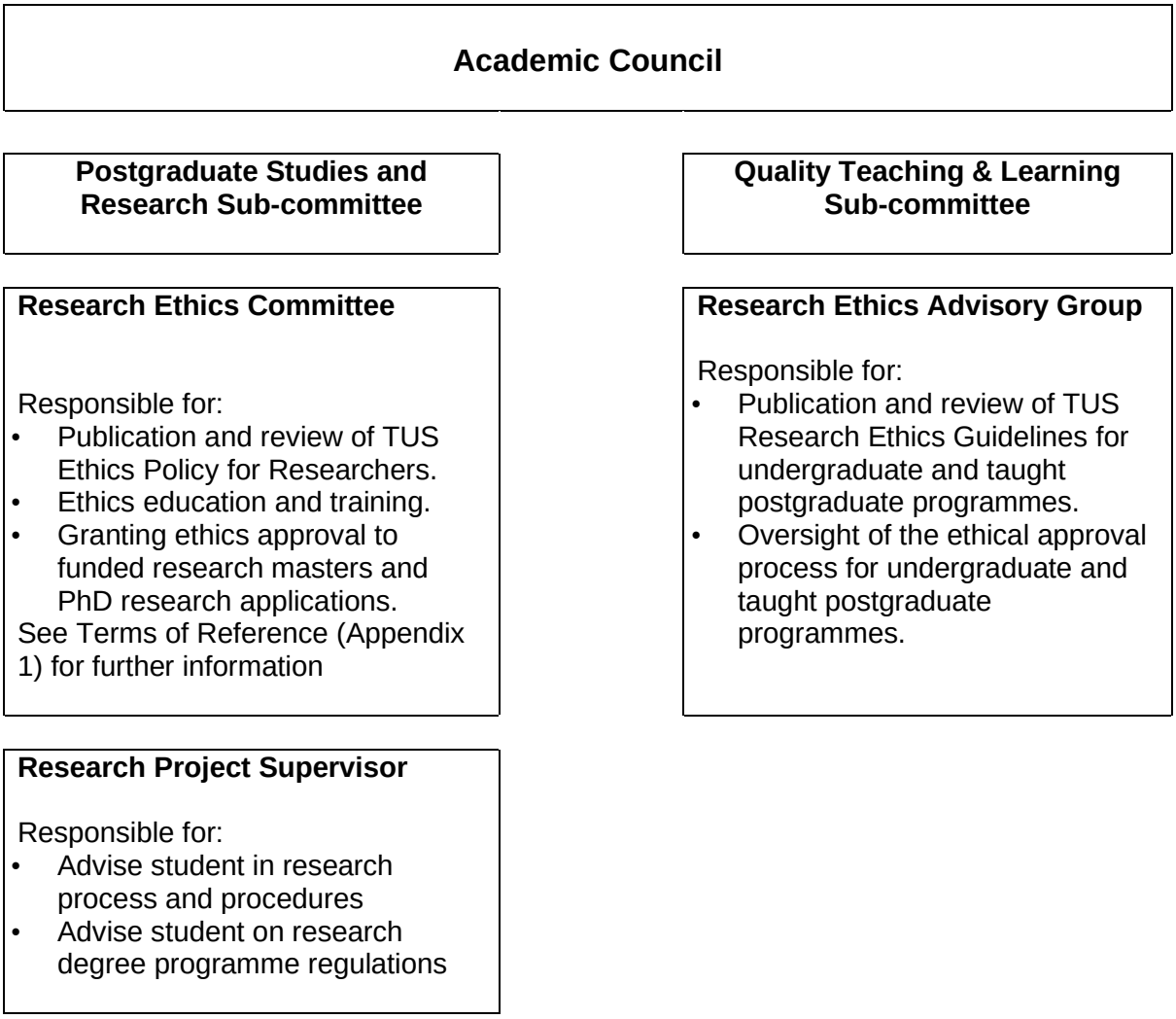


Figure 1: Governance of Research Ethics in TUS

Consent in research is of utmost importance. If you are responsible for, or involved in, planning or conducting research, you must adhere to the appropriate requirements for obtaining consent from participants. Consent for research is the informed, voluntary, and explicit agreement of a potential participant to take part in a research study. This consent must be recorded and kept in accordance with Irish Data Protection Laws. Consent is freely given and unambiguous agreement of the participant to engage in specific research study and/or to allow the processing of their personal data. Participants have the right to withdraw from a research study at any time, without facing any negative consequences.

This right to withdraw should be clearly explained to participants at the start of the research process. There must be no doubt that informed consent was obtained and clearly documented in the consent form.

Capacity is understood as the ability to understand, deliberate and communicate a choice in relation to participating in research. There may be occasions when a participant's state of health may prevent them taking part in the consent process. Health legislation, such as the Assisted Decision-Making (Capacity) Act 2015, the Mental Health Act 2001, should direct best practice. All researchers should treat all people equally without discriminating on the grounds of age, gender, race, religion, civil status, family status, sexual orientation, disability (physical, mental, or intellectual) or membership of an Indigenous community.

Autonomy on behalf of the research participant must be upheld at all times. Intertwined within the autonomous individual is the concept of valid consent which must be given after receiving the relevant information regarding the proposed research. As TUS is ultimately responsible for their students and their staff, it is important that negligence in relation to research is avoided. The "Duty of Care" is owed to all; however, it is vital the Standard of Ethical Approval granted to any research study can alleviate in so far as possible any breaches that may have the potential to cause unforeseeable harm.

Research integrity is essential to ensuring that research is conducted in an appropriate manner reflecting the ethos of trustworthiness. Research practices are based on the principles of integrity ensuring good research quality based on respect for the process, through the implementation of appropriate methodological frameworks; appropriate data collection and analysis and information sharing in a complete and unbiased manner. This lends itself to also having due diligence for colleagues, participants, research subjects, and the societal impact of the findings from the research, whilst also adhering to good sustainability practices. (Please see Appendix 5 for further information)

3.0 Research Ethics Committee

As research is constantly expanding and expanding within TUS, it is essential to obtain and receive Ethical approval from the Research Ethics committee. New developments in research create different ethical dilemmas, expansion of Faculties will also create greater opportunities for conducting research. Ethical standards prevail within the public consciousness and all researchers within TUS have an obligation to the public, to

themselves, to the participants and ultimately to TUS, to ensure that they uphold core ethical principles. The TUS Research Ethics Committee in the Midlands and Midwest will review all applications from TUS research postgraduate students, TUS staff or external researchers accessing TUS students and/or staff. A decision will be made in relation to each application that is received by each committee meeting deadline.

Education offered by the Research Ethics Committee will have an impact on how proposals are viewed and ultimately receive ethical approval. Part of the role will also involve conducting audits to ensure that ethical approval is granted correctly and that the researchers also adhere to the correct procedures in gaining consent from participants and in carrying out the research study.

Ethical support procedures and ethical performance measures will be the focus of the entire committee. The committee will consist of a chairperson; Vice Chairperson; Legal Representative; Faculties Representatives; Lay Person; Ethicist; Information and Data Compliance office representative; Healthcare and appropriate personnel maybe nominated if warranted to discuss a particular issue.

4.0 Ethical Approval Process

The Research Ethics Committees meets monthly during the academic year. Information on meeting dates, and cut-off dates for receipt of items for review, are available to view on Research ethics webpage.

4.1 Application for Preliminary Ethical Approval (Research Postgraduates only)

If the applicant for ethical approval is a research postgraduate student at TUS, then the "TUS Application for Preliminary Ethical Approval by Research Postgraduates" form RE1 must be completed, in consultation with the Principal Supervisor, and submitted to the Research Ethics Committees for their consideration and decision.

Preliminary applications shall be reviewed by 2 members of the Research Ethics Committee. This will be:

The Chair and Vice-chair of the Research Ethics Committee

Or

The Chair/Vice-chair of the Research Ethics Committee and one other member of the Research Ethics Committee

Based on the completed RE1 application, the Research Ethics Committee will provide

Noted– no ethical issues flagged with human participants it is approved;

Or

It requires full application to REC because of human participation.

In practice, the Research Ethics Committee will advise applicants on the ethical issues identified. It is the responsibility of the Research Supervisor to advise the applicant on the documentation and information required in order that preliminary ethical approval can be granted at the earliest opportunity. If the applicant is not satisfied with the decision, they have the right to appeal.

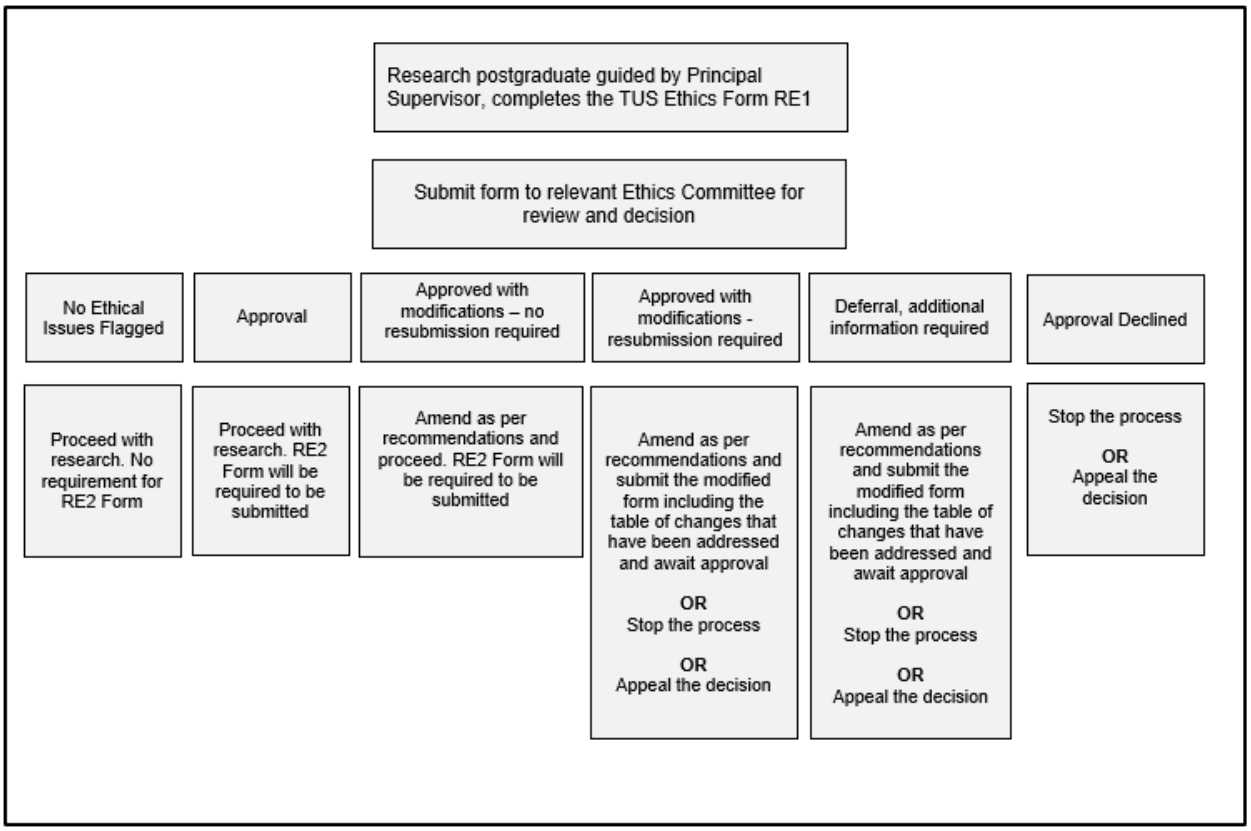


Figure 2: Application Process for Preliminary Ethical Approval (TUS Research Postgraduates only)

4.2 Application Process for Full Ethical Approval

Based on the completed application, the Research Ethics Committee will provide one of the following conclusions:

- No Ethical Issues Flagged
- Approval

- Approved with modifications – no resubmission required
- Approved with modifications - resubmission required
- Deferral, additional information required
- Approval Declined

  Where the Research Ethics Committee approves the application (see decision outcomes below), the research can proceed:

- No Ethical Issues Flagged
- Approval
- Approved with modifications – no resubmission required (The modifications are checked by the Research Ethics Committee)

Where the Research Ethics Committee assess the application on ethical grounds, re-application is required to the Research Ethics Committee before the research can proceed:

- Approved with modifications - resubmission required
- Deferral, additional information required
- Approval Declined

If the submission is approved with modification, the applicant should amend the submission as per the recommendations of the Research Ethics Committee and can proceed with the research unless requested by the Committee to resubmit the revised application.

In the case where a submission requires additional information, or is not approved, the application should be altered as per the recommendations of the Research Ethics Committee and resubmitted for review and decision until such time as ethical approval is granted.
In practice, the Research Ethics Committee will advise applicants on the issues identified. It is the responsibility of the Research Supervisor to advise the applicant on the documentation and information required in order that full ethical approval can be granted at the earliest opportunity. However, the student has every right to invoke the appeals process should they be dissatisfied with the outcome. Section 5 below outlines the appeals process.

4.3 Re-submission

Where an application requires re-submission a list of issues to be addressed will be issued by the Research Ethics Committee. This list or grid should be included in the re-submission, together with an indication as to where each of the issues are addressed in the resubmitted document. Should this summary not be included the resubmission will not be accepted for review.

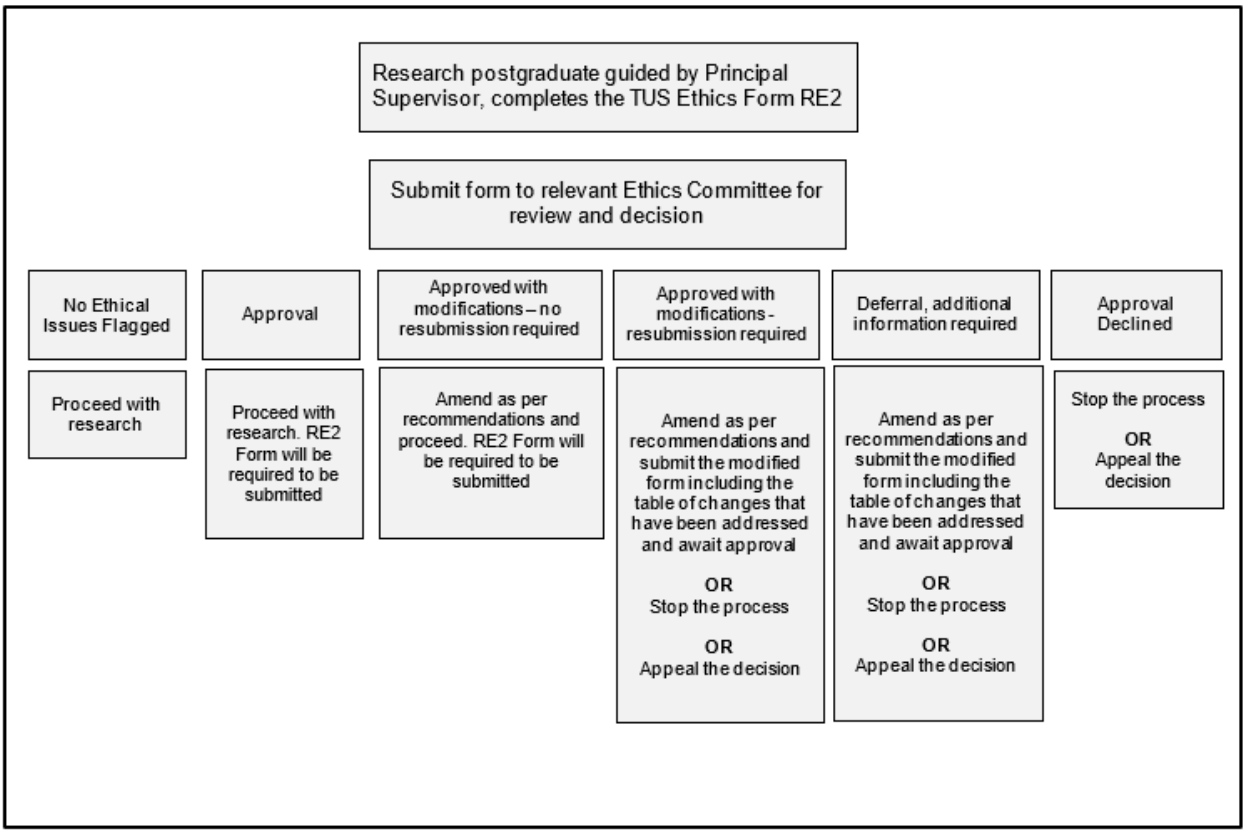


Figure 3: Application Process for Full Ethical Approval (TUS Research Postgraduates, TUS Staff and External Researchers)

5.0 Review of the Research Ethics Committee Decision

To review a decision of the Research Ethics Committee, the applicant must complete the TUS Ethics Review Request Application Form (Appendix 3). The completed form is then submitted to the relevant Research Ethics office via email (ethics.midwest@tus.ie or ethics.midlands@tus.ie). The Review will be evaluated by an Independent Committee. The review should be complete, and a written record of findings should be prepared within fifteen working days of its initiation. If the 15-day deadline cannot be met, a report

should be filed citing progress to date and the reason for the delay and the complainant should be informed. Following the review, the relevant Research Ethics Chair will provide the complainant with a written determination summarising the reasons for the decision reached following the review:

1) The review committee upholds the Research Ethics Committee decision
2) The review committee overturns the Research Ethics Committee decision

6.0 Appeal

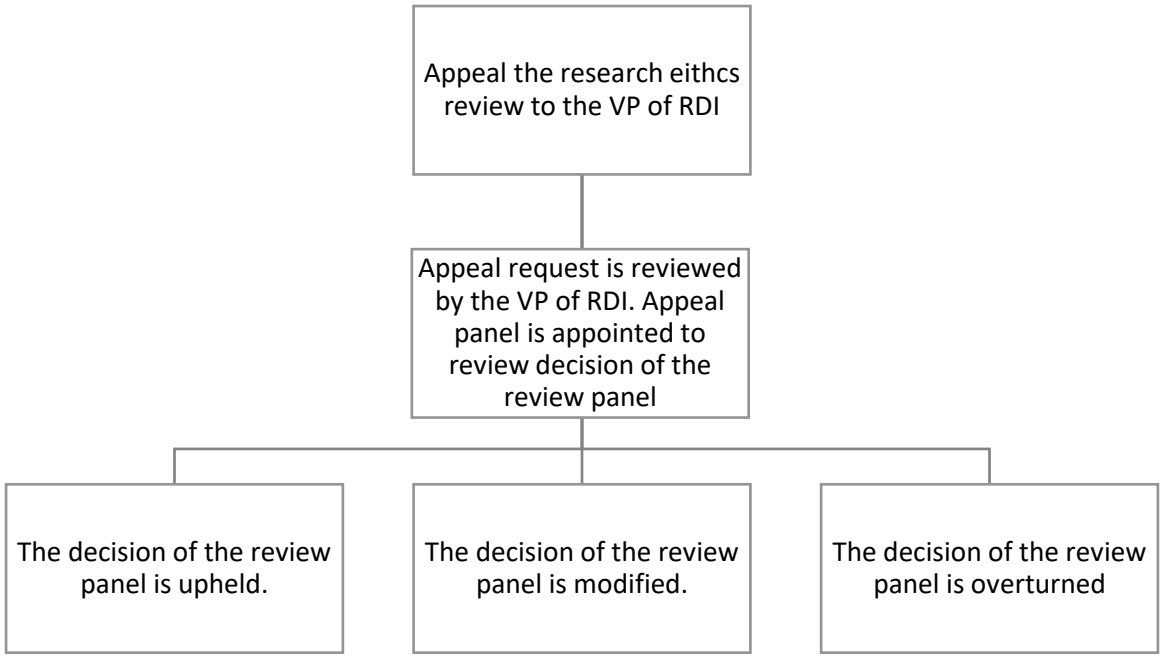
TUS will provide for an appeal process in respect of Research Ethics application outcomes. The purpose of the appeal panel is to;

1) Consider and review the application and internal investigation.
2) Assess if the decisions and actions taken were reasonable in the circumstances;
3) Aim to reach a final internal decision which is fair and just.

The complainant should complete the TUS Appeal Form (Appendix 3), and this form should be submitted to the office of the Vice President for Research, Development and Innovation. This should normally be submitted within ten working days of receipt of the response from the review panel. The appeal should detail the reasons for requesting the findings of the review panel. The Vice President for Research, Development and Innovation will acknowledge receipt of the request within five working days of receipt of the appeal. The Vice President for Research, Development and Innovation, in conjunction with the Research Ethics Chairpersons, shall arrange the appointment of the Appeal Panel and convene a meeting of the panel normally within fifteen working days of receipt of the request. The appeal panel will comprise of a minimum of three appropriately trained senior managers (not involved in the preceding stages). As part of its review, the Panel will have access to all prior records and documents arising from the initial application and review. The Panel may request to meet with all parties involved, individually or collectively as appropriate. Any additional or new information may normally only be submitted if it was reasonably not available during the investigation. However, the Appeals Panel may at its discretion accept new information if it deems it appropriate. The Panel shall endeavor to have completed its review within thirty working days of receipt of the Appeal and has the authority to take the same action as the review panel. Having completed its review, the Panel will decide which may include one or more of the following:

a) upholding the decision of the review panel;
b) modifying the decision of the review panel;
c) overturning the decision of the review panel;

The Appeal Panel's determinations shall be sent within five working days of the conclusion of the review to the relevant party and the relevant Dean of Faculty/School, Head of Department, and the Dean of Graduate Studies. The decision of the Research Ethics Appeal Panel shall be final and binding within the university. This outcome does not interfere with the Statutory Rights of any parties to the application.



7.0 Ownership of Intellectual Property

"Literary Works" means literary works of copyright to the extent created by a Creator during the course of (and/or as part of) his or her employment including, but not limited to, books, articles and other scholarly publications, manuals, slides, audio-visual materials, multi-media materials, musical and artistic materials, on-line content and Teaching and Research Materials (except in the cases of commissioned work, or work developed during or pursuant to a sponsored research or other agreement, or work developed with the use of TUS funds or facilities). Ownership of and intellectual property rights to "literary works" produced by those connected with the university are vested in the individuals involved. Although the Institute makes no claim of ownership to Literary

Works, the Institute reserves for itself and shall maintain a non-exclusive, royalty-free, irrevocable, and perpetual license to use such Literary Works in its teaching and research activities wherever conducted. In the case of "artistic work," the artist retains the copyright to the image. Permission must be sought to reuse the image from the artist independent of who owns or has bought the work. The artist must be credited / acknowledged when publishing the work. The TUS Intellectual Property (IP) Policy is also relevant to IP ownership.

8.0 Ethical Compliance – Responsibilities

8.1 TUS

TUS has established and empowered the Research Ethics Committee (operating under the aegis of the Postgraduate Studies and Research Sub-committee of Academic Council) to discharge its duty and responsibilities in respect of ethical research. TUS is responsible for:

- developing, operating and reviewing policies and guidelines which prevent unethical practices, and which are consistent with recognised standards and best practice in the disciplines (a)
- overseeing the implementation of ethical policies and best practice and supporting researchers who are undertaking research which is ethically sound through implementation of guidance and appropriate supervision (b).
- overseeing the implementation of ethical policies and best practice and supporting researchers who are undertaking research which is ethically sound through review of ethics applications (c).

Figure 4: Ethical Compliance Structure

8.2 Researcher

The ultimate responsibility for conducting ethical research rests with the researcher who should:

- Consider the ethical implications of all projects, including funding source, and conduct all research in accordance with ethical principles. Completing the "TUS Application for Preliminary Ethical Approval" is a good starting point for this process;
- Be aware of, and operate in accordance with, the TUS policies and procedures and professional requirements;
- Be aware of, and operate in accordance with;
    - Policy Statement on Ensuring Research Integrity in Ireland
- Develop and maintain awareness of relevant discipline and professional ethical issues;
- Seek expert advice where appropriate.

The researcher has responsibility for ensuring that appropriate written ethical approval is sought and received from the TUS Ethics Sub-Committee. If researchers are unsure or in doubt as to what is appropriate, they should refer the matter to the Research Ethics Committee. **NOTE: Ethical approval cannot be given retrospectively.**

8.3 Responsibilities of Supervisors/Project Managers/Principal Investigators

The research supervisor(s) for each student is/are responsible for ensuring students are aware of the implementation of procedures and guidelines above. Project managers and directors are responsible for ensuring that research teams are aware of and implement guidance.

8.4 Integrity of the Researcher

- Given the stage of the researcher's career, or in the case of students, the Supervisor's career, they must possess knowledge and skills compatible with the demands of the investigation to be undertaken and must recognise and not overstep the boundaries of their research competence. Researchers should not accept work they are not qualified to carry out or to supervise.
- The researcher has the responsibility to publish or make otherwise available the results of the research, displaying or making available schedules or other research tools and reporting all relevant data, including negative evidence. Limitations about

the validity of the conclusions and the extent to which they can be generalised should be stated.

- Reporting of results must be truthful and accurate.
- As is common practice in any publication, acknowledgements should be made of the contributions of others, but permission must be obtained before names are cited or quotations or acknowledgements made apart from those in already published works, which are governed by copyright.
- The researcher should be aware that they have some responsibility for the use made of the research and should not ignore its misuse.
- The researcher is responsible for adherence to the Code of Ethics/Ethics Policy by members of their team and by any students working under their guidance.

8.5 Responsibility to Participants

- In all circumstances, researchers must consider the ethical implications of their research and the physiological, social, political, and economic consequences of it for the participants. Every effort must be made to assure the protection of research participants against physical, mental, emotional, or social injury. No harm must come to them because of being involved in the study.
- The researcher is responsible for obtaining informed and freely given consent from everyone who is to be a participant of study or be personally involved in a study. The researcher should explain as fully as possible and in meaningful terms to the participants what the research is about, who is undertaking and financing it, and why it is being undertaken. The researcher must make explicit the participant's right to refuse to participate or to withdraw at any stage of the project without penalty, and this right must be respected. When it is not possible to obtain informed consent, for example, vulnerable groups, unconscious patients, specialist advice must be obtained and approval gained from an appropriate Local Research Ethics Committee.
- In the case of children (under 18 years of age)**,** or if the participant is, for any reason, unable to appreciate the implications of participation, informed consent must be obtained from parents or legal guardian. An agreed consent form should be signed in all cases. This form must be approved for use by the TUS Research Ethics Committee. (Please see HSE National Consent Policy).

- If the participants are being accessed as patients or information is being abstracted from medical records, then the guidelines of the relevant Health Services Executive Area Research Ethics Committee, Hospital Research Ethics Committee, Health Research Board Ethics Policy, and Bioethics Policy should be followed.
- If the nature of the research is such that fully informed participants before the study would invalidate results, then whatever explanation is possible should be given to the participants. There must be provision for appropriate explanation and debriefing to the participants on completion of the study.
- An investigator should seek the opinion of experienced colleagues whenever their research requires or is likely to involve:
    - psychological or physiological stress, or
    - encroachment on privacy.
- Please note that an investigator will not be permitted to proceed where research requires, or is likely to involve, deception or covert data collection.
- All participants in all studies must be informed of the nature of the study and their consent obtained. There may be occasions where investigations compare standard interventions (or care or education) with new or other interventions to be tested. In these cases, all participants must be informed of the nature of the study and debriefing, or an option to receive the new intervention should normally follow participation as a matter of course.
- Explanations to participants should include information as to how their names came to the knowledge of the researcher. Researchers should identify themselves and the organisation responsible for the study and provide participants a written note giving this information, together with a brief statement concerning the nature of the study.
- The nature of any assurance of confidentiality or anonymity, or restrictions on the use of information, must be strictly adhered to and made clear to the participants. Particular attention must be given to the university's Intellectual Property Policy and procedures and any contractual, Intellectual Property, Non-Disclosure Agreement or Confidentiality Agreements with any third parties. Conflicts of interest must always be declared as per university Conflict of Interest Policy.
- The researcher should be aware that the use of records can present problems in relation to confidentiality.

8.6 Responsibilities of Data Collectors and Data Transcribers

Sub Sections 8.6 provide general guidance to Data Protection standards please refer to TUS Data Protection Policy for full information.

- Researchers have an obligation to make clear to their employers or sponsors that they cannot undertake work outside their research competence and to decline work where limitations of competence or facilities in terms of money, time, personnel, or equipment are such as to make the achievement of the research aims impossible.
- The researcher must make clear to his or her employer or sponsor that 'solutions' to problems cannot be guaranteed and should make explicit the limitations of the proposed research.
- The terms under which research is being carried out should be stated in a clear way with as much detail as possible to avoid misunderstanding.
- When processing personal data, researchers must place all the appropriate security and other data protection safeguards for the information which is released to them. Informal and ad-hoc arrangements will not be acceptable where personal data released to or by TUS or its agents is involved. Written evidence of these procedures must be in place.
- On each occasion where TUS or its researchers releases or receives data, specific instructions must be provided on how the personal data provided is to be processed. Personal data can only be processed on the basis of this authorisation and instruction. At all times personal data passed to or from TUS may not be retained or used by the data processor for its own purposes and all data and information arising from the processing of the data must be deleted once the data has been processed.
- Appropriate security measures must be applied to personal data to protect it from unauthorised access or disclosure. Ensuring at all times that confidentially and protection of is maintained.
- All data released to TUS must be deleted upon termination or ending of the research or contract.
- For data to be released by or to TUS, indemnity must be established in advance for all losses arising from unauthorised access or disclosure of information.
- In certain circumstances TUS or TUS researchers may have to register as a Data Processor with the Office of the Data Protection Commissioner for the duration of the research or contract.

8.6.1 Managing Personal Data

- Personal data is any data that can be used either on its own or in combination with other information to identify a living individual. Obvious examples of personal data include name, identification number, address, and telephone number. Less obvious examples include political opinions, location data, biometric data such as fingerprints and the IP address of a device used by an individual. A person may also be identifiable by reference to factors that are specific to their identity, such as physical, genetic, or cultural factors.
- Personal data is protected under data protection legislation. Where research involves the use of personal data, we need to ensure that we comply with this legislation.
- The following guidelines should always be adhered to when research involves the use of personal data. The guidelines are written as a checklist for researchers:

    1) Make a list of each item of personal data you require for your research.
    2) Record the reason that you need each item of personal data. The use of personal data must be necessary and proportionate. You should only request personal data for which your research has a specific need. It is not permissible to request personal data 'in case' you might need it. Minimise the amount of personal data you gather.
    3) Document the source of the personal data. Is the individual providing you with the data directly or are you collecting it from a different source? If you are obtaining the personal data from a different source, get confirmation from the source that they have permission to share it.
    4) Are you collecting special category data? Special category data is personal data relating to any of the following:
        a) Racial or ethnic origin
        b) Religious or philosophical beliefs
        c) Political opinions
        d) Trade union membership
        e) Biometric data used to identify an individual
        f) Genetic data
        g) Health data

h) Data relating to an individual's sex life or sexual orientation

Special category data receives additional protection under data protection legislation and the researcher must take additional security precautions when using such data.

- You must be transparent with the participant as to why you are collecting their personal data. At the outset of your research, clearly explain to participants (a) who you are (b) what the research relates to (c) whether you will share personal data gathered with any other party (d) the security measures you will use to safeguard the data (e) where you will store the data and (f) how long you will keep the data for.
- Where you are using interviews with participants as a means of gathering information for your research, you must inform them at the outset if you intend including transcripts of interviews in your research.
- Obtain the consent of the individual to participate in the research. The individual must provide explicit and informed consent to participate in the research. Explicit means that the individual must take an action to indicate consent; you cannot use a pre-ticked box or assume consent. If you are using a survey to gather information, include a tick box question asking the participant if they are happy to proceed with the survey. Informed consent means that you must comply with the transparency rules. See point 5 above. Tell participants that they have the right to withdraw their consent at any time. You must be able to demonstrate that you obtained an individual's consent to participate in the research i.e. your method of collecting consent must be auditable.
- If you are unable to obtain consent from individuals participating in your research or you believe that consent is not an appropriate mechanism for your research, contact the Information and Data Compliance Office datacompliance@tus.ie.
- Protect the data. One of the methods you can use to protect personal data is to anonymise it. Anonymising data means that you irreversibly delete any uniquely identifying fields. For example, if you have used a survey to gather responses, you can anonymise the data by securely deleting the name or any other identifying data from the dataset. It should never be possible to attribute survey responses to an individual after anonymisation.
- Where anonymisation is not possible, you can pseudonymise the data. This means that you remove obviously identifying information from the dataset e.g. name or identification number. This identifying information should be kept separately to the

main dataset. The identifying information should be protected (e.g. kept in a password protected file) and only be accessible by the researcher.

- For all data, including that which has been anonymised and pseudonymised, you must take appropriate security precautions to protect the data. Hard copies of data must be kept in locked cabinets. Soft copies must be stored on a password-protected computer/laptop or encrypted external storage device. Where data is being stored in the cloud, be aware of the level of encryption provided and the measures taken to secure encryption keys.
- Are you collecting children's data i.e. personal data relating to individuals under the age of 18? If so, you must obtain the consent of a parent or guardian for the use of that data.
- Decide how long you will retain the data for. Personal data must not be held for longer than is necessary. The retention period must be outlined to participants at the outset of your research.
- Consider how you will dispose of personal data that is no longer required. You must ensure deletion or disposal of data in a secure manner e.g. for hard copy data use the confidential shredding bags supplied by the Institute. Ensure that you dispose of both hard and soft copies of data.

8.6.2 Data Ownership and Custody

As research produces data, it is envisaged that the researcher(s) who conducts the research owns the product of that research, including the data. This common understanding should prevail unless there are explicit conditions specified as part of any commissioned and/or funded research by third parties which delineates alternative ownership of data. Ownership does not imply custody. Unless stipulated otherwise, custody of the data remains with the researcher during the conduct of the research. On completion of the research project, custody of the data transfers to TUS. Explicit transfer of the data that was used in a researcher's project should be collated and transferred to TUS when the research has been completed and ownership of the data transfers to TUS. This may include hard copy files and/or computer files.

8.6.3 Data Collection

The nature of the research, and its design, dictates the type of data collection technique to be adopted. Irrespective of the specific type of data collection technique, some

common principles prevail in relation to ethical data collection that will ensure that the overall integrity of the data collection process, and the information collected, is ensured. These include:

1) authorisation to collect data in advance of proceeding
2) the use of appropriate methods of data collection – to have reliable research via its data then appropriate, reliable, and controlled methods should be used
3) attention to detail - the data collected should be suitably and accurately recorded, and then interpreted
4) recording of data correctly - the permanent record of the data collected should be managed to ensure it is auditable and traceable irrespective of the storage device used.

8.6.4 Data Sharing

- During the period of ownership of the data by the researcher, they are not allowed share the data via any mechanism with any other third party unless authorised to do so. Consent to share the data must be formally obtained from participants in the research whose data is to be shared. Retrospective authorisation to share data is not appropriate and does not exempt the researcher from unauthorised sharing of data. Research data must be available to respond, if required, to Freedom of Information requests. It is the responsibility of the data owner to ensure such data is available.
- Research data that includes personal data or is subject to Section 39 of the Freedom of Information Act 2014, is not permissible to share.

8.6.5 Data Storage and Security

The researcher who collects and uses research data has the primary responsibility for it. All data collected and used should be adequately stored to ensure it is not accessed inappropriately, damaged, lost, or stolen. The stored data must be kept in a secure and protected state, and in accordance with TUS Data Retention and Records Management Policy during its lifetime of existence. All data that is subject to privacy conditions requires adequate and secure storage. This may require the encryption of data. All data that includes the storage of the personal data of participants must be encrypted. Data should only be accessible by the researcher and other pre-authorised personnel such as a Research Supervisor. All data collected must be stored in a safe and secure place by the researcher during their period of ownership of the data. At the time of transfer of

ownership to TUS, the researcher must ensure that all data collected is transferred in soft copy to a suitable storage device. This device should then be given to TUS when the period of ownership by the researcher is deemed by the Research Project Supervisor to have terminated.

8.6.6 Data Retention

- Custody of the data must be retained by the parent academic department which managed the conduct of the researchers on its completion and when ownership of the research data passes to TUS. The data can only be stored and retained for the period explicitly notified to the participant at the outset of the study. To that end, data retention in a secure and protected state, should be in accordance with TUS Data Retention and Records Management Policy.
- A central repository listing all records of the storage devices that are being retained the parent academic department of the researcher should be maintained. The reference details recorded should include details of the name, registration number, programme of study, date of completion of programme, and date of receipt of storage device.

All Researchers must comply with:

- Data Protection Act 2018 and Amendments
- Freedom of Information Act 2014
- TUS Data Protection Policy
- TUS Freedom of Information Guidelines

9.0 Research Activity Prohibited at TUS

Research activity prohibited at TUS is guided by "REGULATION (EU) No. 1291/2013" of the European parliament (Ref. Article 19).

Article 19 Ethical principles Preamble
Research and innovation activities supported by Horizon Europe should respect fundamental ethical principles. The opinions of the European Group on Ethics in Science and New Technologies should be considered. Article 13 TFEU should also be considered in research activities, and the use of animals in research and testing should be reduced,

with a view ultimately to replacing their use. All activities should be carried out ensuring a high level of human health protection in accordance with Article 168 TFEU.

The Commission does not explicitly solicit the use of human embryonic stem cells. The use, if any, of human stem cells, be they adult or embryonic, depends on the judgment of the scientists in view of the objectives they want to achieve and is subject to stringent ethics review. No project involving the use of human embryonic stem cells should be funded that does not obtain the necessary approvals from the Member States. No activity should be funded that is forbidden in all Member States. No activity should be funded in a Member State where such activity is forbidden.

Article 19 Ethical principles

All the research and innovation activities carried out under Horizon Europe shall comply with ethical principles and relevant national, Union, and international legislation, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols.

1) Particular attention shall be paid to the principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of a person, the right to non-discrimination and the need to ensure high levels of human health protection.

2) Research and innovation activities carried out under Horizon 2020 shall have an exclusive focus on civil applications.

3) The following fields of research shall not be financed:

   a) Research activity aiming at human cloning for reproductive purposes.
   b) Research activity intended to modify the genetic heritage of human beings which could make such changes heritable.
   c) Research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

4) Research on human stem cells, both adult and embryonic, may be financed, depending both on the contents of the scientific proposal and the legal framework of the Member States involved. No funding shall be granted for research activities that are prohibited in all the Member States. No activity shall be funded in a Member State where such activity is forbidden.

5) The fields of research set out in paragraph 3 of this Article may be reviewed within the context of the interim evaluation set out in Article 32(3) of the Midterm Evaluation of Horizon 2020 in the light of scientific advances.

Reference List

Council of Europe (1950). European Convention on Human Rights.

European Commission (2017). Interim Evaluation of Horizon 2020 (Article 32 (3)).

European Parliament (2007). Charter of Fundamental Rights of the European Union.

European Parliament (2017). EU framework programmes for research and innovation (Article 19).

European Union (2009). Treaty on the Functioning of the European Union (Article 13).

European Union (2009). Treaty on the Functioning of the European Union (Article 168).

Health Service Executive (2024*).* National Consent Policy.

House of the Oireachtas (2022). Assisted Decision-Making (Capacity) (Amendment) Act 2022.

House of the Oireachtas (2018). Data Protection Acts 1988 to 2018.

House of the Oireachtas (2014). Freedom of Information Act 2014.

House of the Oireachtas (2001). Mental Health Act 2021.

Irish Universities Association Policy (2024). Statement on Ensuring Research Integrity in Ireland.

TUS (2022). Conflict of Interest Policy.

TUS (2023). Data Protection Policy.

TUS (2023). Data Retention and Records Management Policy.

TUS (2022). Intellectual Property Policy.

TUS (2025). Research Integrity Policy.

APPENDIX 1 Terms of Reference of TUS Research Ethics Committee

ACADEMIC COUNCIL SUB-COMMITTEE ON RESEARCH & POSTGRADUATE MATTERS

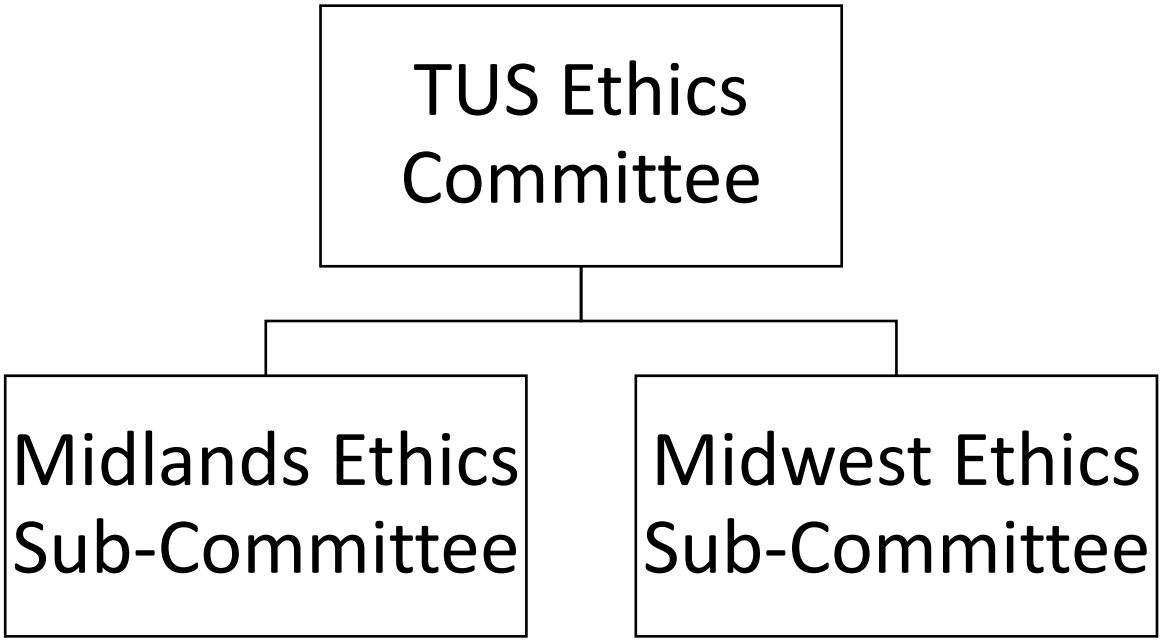
RESEARCH ETHICS COMMITTEE

TERMS OF REFERENCE

1. Reporting Line:

The Research Ethics Committee reports to the Postgraduate Studies and Research Sub-Committee of the TUS Academic Council and assists in the realisation of its responsibilities for ethics in research carried out within the TUS.

Taking into consideration the diverse geographical location of TUS campuses and wishing to be inclusive it is at the discretion of the Committees to hold these meetings remotely.



TUS RESEARCH ETHICS COMMITTEE

1. General Responsibilities

The TUS Research Ethics Committee of the Academic Council Sub-Committee on Postgraduate Studies and Research shall have general responsibility for:

1.1 Developing and monitoring of the TUS Research Ethics Policy and Procedures and advising the Academic Council Sub-Committee on Postgraduate Studies and Research on matters related to Research Ethics.

1.2 Reviewing and deciding on applications for ethical approval with respect to:

- TUS Postgraduate research degree programmes that have been referred by the ethics sub-committees
- TUS staff researchers accessing TUS staff and students
- External researchers accessing TUS staff and students
- Research being carried out by staff members of TUS within the TUS
- Research being carried out by staff members of TUS on behalf of the TUS
- TUS staff conducting independent research which does not have ethical approval from elsewhere and who wish to obtain approval from a Research Ethics Committee

2. Function

The TUS Research Ethics Committee will have the following responsibilities:

2.1 Review applications that have been referred by the ethics sub-committees and adjudicate on those for ethical approval to collect research data in line with TUS Research Ethics guidelines and communicating the outcome of the adjudication to the researchers.

2.2 Advising the Postgraduate Studies and Research sub-committee on developing and administering the TUS regulations regarding Research Ethics.

2.3 Reviewing the Research Ethics Policy and procedures for monitoring standards of Research Ethics in relation to TUS Policy.

2.4 Liaising with other working groups of the Postgraduate Studies and Research sub-committee and other sub-committees of TUS, and Academic Council, in relation to *Research Ethics*.

2.5 Providing research supervisor training programmes on research ethics at TUS.

2.6 Promoting awareness of research ethics among researchers at TUS.

2.7 Implementing Research Ethics policies and procedures in line with other TUS policies as they develop.

3. Reporting

3.1 The Research Ethics Committee will report to the Postgraduate Studies and Research sub-committee as appropriate, but not less than once a year and will submit an annual report on all activities carried out under the above terms of reference.

3.2 The Chairperson or their nominee will be responsible for reporting the decisions and views of the Research Ethics Committee to the Postgraduate Studies and Research sub-committee, and for transmitting the relevant decision and views of the sub-committee to the Research Ethics Committee.

4. Frequency of Meetings

The Research Ethics Committee shall meet at least once per semester, and at such other times as required.

5. Key Documentation Informing the Research Ethics Committee

- TUS Ethics Policy for Researchers
- TUS Research Integrity Policy
- TUS Research Degree Programme Regulations

6. Specific Research Ethics Committee Membership

Membership of the Research Ethics Committee shall normally consist of:

- Rotating Chair from the Chairs of the Research Ethics Sub-Committees
- Rotating Vice Chair from the Vice Chairs of the Research Ethics Sub-Committees
- Chair of the Research & Postgraduate Matters sub-committee
- Head of Research & Technology Transfer
- Graduate Research Office Member
- At least one representative from each Faculty/School/Department within the TUS
- Nominee from the Registrar's Office

- Data Compliance Officer
- A member with legal expertise

Additional members from the staff of the TUS or external to the TUS may be co-opted and other persons (including external experts) may be invited to attend as advisors for periods of time or for specific purposes.

NOTES:

Co-options shall be made only with the majority approval of the Research Ethics Committee

TUS ETHICS SUB-COMMITTEES

7. General Responsibilities

The Research Ethics Sub-Committees shall have general responsibility for:

7.1 Contributing to the developing and monitoring of the TUS Research Ethics Policy and Procedures and advising the Academic Council Sub-Committee on Research and Postgraduate Matters on matters related to Research Ethics.

7.2 Reviewing and deciding on applications for ethical approval with respect to:

- TUS Postgraduate research degree programmes
- Desktop review (in exceptional cases) – to facilitate where there is a time deadline to be met.

Preliminary applications shall be reviewed by 2 members of the Research Ethics Sub-Committee. This will be:

- The Chair and Vice-chair of the Research Ethics Sub-Committee

Or

- The Chair/Vice-chair of the Research Ethics Sub-Committee and one other member of the Research Ethics Sub-Committee

8. Function

The Research Ethics Sub-Committee will have the following responsibilities:

8.1 Review and adjudicate on applications for ethical approval to collect research data in line with TUS Research Ethics guidelines and communicating the outcome of the adjudication to the researchers.

8.2 Advising the Research Ethics Committee on developing and administering the TUS regulations regarding Research Ethics.

8.3 Reviewing the Research Ethics Policy and procedures for monitoring standards of Research Ethics in relation to TUS Policy.

8.4 Liaising with other working groups of the Postgraduate research sub-committee and other sub-committees of TUS, and Academic Council, in relation to *Research Ethics*.

8.5 Providing information on Research Ethics procedures, policies, and processes to research postgraduates in TUS.

8.6 Contributing to research supervisor training programmes on research ethics at TUS.

8.7 Promoting awareness of research ethics among researchers at TUS.

8.8 Implementing Research Ethics policies and procedures in line with other TUS policies as they develop.

9. Reporting

9.1 The Research Ethics Sub-Committee will report to the TUS Research Ethics Committee as appropriate, but not less than once a year and will submit an annual report on all activities carried out under the above terms of reference.

9.2 The Chairperson or their nominee will be responsible for reporting the decisions and views of the Research Ethics Sub-Committee to the TUS Research Ethics Committee, and for transmitting the relevant decision and views of the TUS Research Ethics Committee to the Research Ethics Sub-Committee.

10. Frequency of Meetings

The Research Ethics Sub-Committee shall meet at least once per semester, and at such other times as required.

11. Key Documentation Informing the Research Ethics Sub-Committee

- TUS Research Ethics Policy Document
- TUS Research Integrity Document
- TUS Research Degree Programme Regulations

12. Specific Research Ethics Sub-Committee Membership

Membership of the Research Ethics Committee shall normally consist of:

- Chair of the Research Ethics Sub-Committee
- Vice Chair of the Research Ethics Sub-Committee
- Chair of the Research & Postgraduate Matters sub-committee
- Head of Research & Technology Transfer
- Graduate Research Office Member
- At least one representative from each Faculty/School/Department within the TUS
- Nominee from the Registrar's Office
- Data Compliance Officer
- A member with legal expertise

Additional members from the staff of the TUS or external to the TUS may be co-opted and other persons (including external experts) may be invited to attend as advisors for periods of time or for specific purposes.

NOTES: Co-options shall be made only with the majority approval of the Research Ethics Sub-Committee

Ethics Committee and Sub-Committees

13. Standing Orders for the Meetings

Notice: Notice of all meetings shall be circulated to each member of the Committee, Sub-Committees with the agenda and background information, at least ten working days before the date of the meeting.

Quorum: A quorum will constitute four members, one of whom shall be the chairperson/vice chairperson plus external expertise if required will be invited in an advisory capacity who are not part of the quorum.

If the chairperson or vice chairperson is not present the business shall not be transacted at that meeting and shall be transacted at the next meeting or on such other day as the chairperson shall appoint.

If a quorum is not present or if during the meeting the numbers present fall below the quorum the business will be transacted at that meeting but shall not be finalised. All decisions, minutes etc. shall be circulated to the members who were unable to attend or remain for their comment and input. This will be circulated within 3 working days and the members who were unable to attend will return their comments within 5 working days.

Invitation: Non-members or external authorities/organisations/individuals may be invited by the chairperson to attend individual meetings but will not have voting rights.

Duration: All meetings shall be of a maximum duration of 3 hours. Any business not transacted at that meeting shall be transacted at the next meeting or on such other day as the chairperson shall appoint.

Confidentiality: A member of the committee shall not disclose to any person not a member of the same committee, any business of that group. In practice, this means that any decisions taken by the committee can and will be reported through the approved channels only. The discussions around any decision cannot be disclosed. All members of the committee are bound by confidentiality agreement which will govern proposals submitted, discussions during the meetings and responses given to researchers.

Attendance: A group member who is absent from four consecutive meetings, or one academic year unless absence was due to illness or has been approved in advance by the committee or sub-committees, shall be deemed to have resigned and shall be replaced by a co-opted member for the remainder of that person's period in office.

Resignation: An elected or nominated member may resign at any time from membership of a committee or sub-committees. This must be in writing, to the chairperson of the committee or sub-committees, and shall be deemed to take effect from the date of receipt by the chairperson of the letter of resignation.

APPENDIX 2 Form to Review a Decision of the Research Ethics Committee

PLEASE COMPLETE ALL SECTIONS – ENTER N/A IF NOT APPLICABLE

TUS Ethics Review Request Form	
Applicant Name:	
Faculty/Department:	
Research Centre or Group:	
Principal Supervisor:	
Award Sought:	
Title of proposed research:	
Reference Number:	

Reason for Appeal:

SIGNATURE OF APPLICANT: _____
DATE: _____

SIGNATURE OF PRINCIPAL SUPERVISOR: _____
DATE: _____

Please submit completed form to the relevant Research Ethics office;
ethics.midwest@tus.ie or ethics.midlands@tus.ie

Outcome of Review:		
Supports the original decision of the Research Ethics Committee	YES	NO
Overturn the original decision of the Research Ethics Committee on procedural grounds	YES	NO

Reason(s) for Decision/Specified Adjustments to the Procedures:

SIGNATURE OF Chair of TUS Research Ethics Committee:

_____

DATE: _____

APPENDIX 3 Form for Research Ethics Appeal

PLEASE COMPLETE ALL SECTIONS – ENTER N/A IF NOT APPLICABLE

TUS Research Ethics Appeal Request	
Applicant Name:	
Faculty/Department:	
Research Centre or Group:	
Principal Supervisor:	
Award Sought:	
Title of proposed research:	
Reference Number:	

Reason for Appeal:

SIGNATURE OF APPLICANT: _____
DATE: _____

SIGNATURE OF PRINCIPAL SUPERVISOR: _____
DATE: _____

The completed form is then submitted to the office of the Vice-President of Research, Development an Innovation

Outcome of Appeal:		
Reviewers supports the decision of the review panel	YES	NO
Reviewers overturns the decision of the review panel	YES	NO
Reviewers modify the decision of the review panel	YES	NO

Reason(s) for Decision/Recommendation:

APPEAL PANEL CHAIRPERSON SIGNATURE:

_____

DATE: _____

APPENDIX 4 Good Research Integrity Practices and Guiding Principles

TUS adheres to implementing the following guidelines as best practice.

Charter of Fundamental Rights of the European Union

Article 3: Right to the integrity of the person

1. Everyone has the right to respect his or her physical and mental integrity.
2. In the fields of medicine and biology, the following must be respected in particular:
    - the free and informed consent of the person concerned according to the procedures laid down by law,
    - the prohibition of eugenic practices, particularly those aiming at the selection of persons,
    - the prohibition on making the human body and its parts as such a source of financial gain,
    - the prohibition of the reproductive cloning of human beings.

Article 8: Protection of personal data

1. Everyone has the right to the protection of personal data concerning him or her.
2. Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.
3. Compliance with these rules shall be subject to control by an independent authority.

Article 13: Freedom of the arts and sciences

The arts and scientific research shall be free of constraint. Academic freedom shall be respected.

Treaty of the Functioning of the European Unions (TFEU)

Article 13:

In formulating and implementing the Union's agriculture, fisheries, transport, internal market, research and technological development and space policies, the Union and the Member States shall, since animals are sentient beings, pay full regard to the welfare requirements of animals, while respecting the legislative or administrative provisions and customs of the Member States relating in particular to religious rites, cultural traditions and regional heritage.

Article 168:

A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities etc.

Respect will be based on the Universal Declaration of Human Rights (1948) which recognizes the inherent dignity and equality of all human beings also recognizing the various legal frameworks that exist such as the European Convention for the Protection of Human Rights and Fundamental Freedoms (Council of Europe, 1950), the Constitution of Ireland (Government of Ireland,1937), the Equal Status Acts (Government of Ireland, 2000–2018 and the United Nations Convention on the Rights of Persons with Disabilities, 2007 (ratified by the Government of Ireland, 2018).

In addition to the guidance provided below, it is recommended that TUS researchers familiarise themselves with the following documents for additional guidance on conducting ethical research: The European Commission's "Guidance: How to complete your ethics self-assessment" document.

In summary, research should be undertaken in accordance with commonly agreed standards of good practice, such as those laid down in the Declaration of Helsinki.

- Beneficence – 'do positive good'
- Non-Maleficence – 'do no harm'
- Informed consent
- Confidentiality/Anonymity
- Veracity 'truth telling.'

Beneficence and Non-Maleficence

- Concerns risk(s), harm and hazards, and includes emotional and mental distress, damage to financial and social standing as well as physical harm.
- The research should be scientifically sound, and the purpose should be to contribute to knowledge.
- The research should be undertaken and supervised by those who are appropriately qualified and experienced.
- The importance of the objective should be in proportion to the inherent risk to the participants. Concern for the interests of the participants must always prevail over the interests of science and society.
- The research should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the participants or to others.
- Research should not be undertaken where the hazards involved are not believed to be predictable.
- Adequate facilities and procedures should be in place to deal with any potential hazards.

Research Competence

- The researcher should have the relevant education, training, and competence to conduct the intended research.
- The researcher should have the relevant professional skill necessary to work appropriately with the population of interest in a research capacity
- The researcher should be honest in terms of their communications, data collection, data reporting, usage or methods and procedures applied in planning and conducting their research
- The researcher should be of strong personal integrity to ensure the quality of being honest in all aspects of the research and have strong professional and ethical standards.
- The researcher is deemed to have constructive knowledge of the relevant and governing laws institutional and government policies as they relate to academic research
- The researcher should be aware that rights are legal, social, or ethical principles of freedom or entitlement; that is, rights are the fundamental normative rules about what is allowed of people or owed to people, according to some legal system, social convention, or ethical theory.

Informed Consent

Ethically, informed consent is part of the principle of respect for autonomy. Rights of self-determination and “not to be harmed” are implicit in the European Convention on Human Rights. Furthermore, the primary consideration in any research within health and social care is preserving the dignity, rights, safety and well-being of participants and that informed consent is at the heart of ethical research.

- Each potential participant must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the research and any discomfort participation may entail;
- Any documentation given to potential participants should be comprehensible and there should be an opportunity for them to raise any issues of concern, in a private and confidential environment if so required;
- Consent should be required in writing and records of consent should be maintained;
- Potential participants must be informed that they are free to withdraw consent to participation at any time;
- There should be a procedure for making complaints and participants should be made aware of this;

- All participants should be volunteers. Considerable care should be taken where consent is sought from those in a dependent position, and it should be made clear that refusal to participate will not lead to any adverse consequences. For example, students must be assured that any decision not to participate will not prejudice, in any way, their academic progress;
- Any inducement offered to participants should be declared and should be in accordance with appropriate guidelines;
- Specialist advice and appropriate approval should be sought where necessary.

In addition, where participants are vulnerable, for example children (under 16 years of age – new HSE guidelines 2025), the frail elderly, and when the participants' capacity to consent is in doubt, specialist advice should be obtained.

Participants in a Research Study must give their Informed Consent before Participating

- Participants should understand the purpose and nature of the study, what participation in the study requires, and what benefits are intended to result from the study (see Section 6.3.3 for special guidance on vulnerable participants).
- Voluntary informed consent, in writing, should usually be obtained from any participant who is able to give such consent.
- It is the researcher's responsibility to seek on-going consent during the course of a study.
- Consent may be implied by the completion and return of many social survey questionnaires, removing the need for written consent.
- Individual consent may be unnecessary for some research activities, such as community research, which may be quite un-intrusive, for example studies involving observation of public behaviour. However, researchers need to consider the privacy of individuals and groups involved, the right of privacy must be respected, and researchers need to ensure that the research does not run counter to the Human Rights Act 1998, Article 8 (Right to respect for private and family life).

Where Third Parties are affected by the Research, Informed Consent required

- When third parties, for example, spouses, teacher, or health care professionals, are directly involved in the care, education or treatment of the potential participants, consent should also be obtained from them.
- Informed consent should involve sharing of information about the project.

- If the proposed research is likely to interfere with the treatment or care being provided by a third party, it is necessary that they be fully informed and sign a consent to participate form.
- In certain situations, the affiliation of participants to particular organisations or special groups such as educational institutions, business organisations, or hospitals, may necessitate the granting of permission to conduct the research project and any relevant policies or guidelines should be followed.

The Consent of Vulnerable Participants or their Representatives' Consent

The consent of vulnerable participants or their representatives' consent must be sought by researchers. If the involvement of children (under 16 years of age) in a research study is justified, then parents or other legal guardians must be informed and to give their consent for inclusion of the child in the study. Assisted Decision-Making (Capacity) Act (2015) must be complied with.

Right to be Known

In some cases, participants in research may wish to have their participation acknowledged in the final research report and in subsequent papers. This is only possible if the terms laid out in the information and consent forms that are approved by the Research Ethics Committee. It is not permissible for participants to waive their right to confidentiality and anonymity after data has been analysed.

Re-analysis of Data (see Section 7.10)

Some funding sources may require that data collected should be available for reanalysis by subsequent researchers. If this is a requirement of data collected from human research participants, researchers should make this clear in the information that they provide to participants. They should also ensure that participants consent to potential future reanalysis of data by a researcher other than the primary data collector. Anonymity and confidentially must be maintained.

On-going Permission for Additional Data Collection

When collecting data using methods which build on the data as it is collected, for example in the use of grounded theory, each separate approach to data collection must be approved by the Research Ethics Committee. Similarly, if the approach to data collection needs to change during the study, additional permission must be obtained before further data is collected.

Research Based on Human Tissue, or Collections of Human Material

Samples of human tissue may be obtained from volunteers, from patients or from people who have died. This type of research has a contribution to make in developing therapy or adding to scientific knowledge. Human material also has an important role in diagnosis, medical training or in public health for example by the examination of historical collections. The purpose of this type of research can be described as *therapeutic.*

Human tissue and remains can also be used in a research context for *non- therapeutic* purposes. Human material can be used for forensic purposes, with examination made of human remains to establish cause of sudden death, unnatural or violent death, for example war crimes. In addition, this type of research may aim to identify previously unidentifiable collections. Human material in this present document refers to biological material of human origin, including organs, tissues, bodily fluids, teeth, hair and nails and substances extracted from such material such as DNA. It can be distinguished into four groupings:

- Research on new collections and research using reused samples;
- Material obtained from living donors and material taken from people who have died;
- Human material donated solely or partly for research and material left over following diagnosis and treatment;
- Unclaimed and unidentified organs and tissue (includes bones).

General Guiding principles

- Research should only go ahead if the potential benefit outweighs risk to donors of the samples;
- The human body and its parts should be treated with respect and should be treated as gifts;
- Samples of biological material obtained for use in research should be treated as gifts. Donors' wishes should be respected when using the material;
- The human body and its parts shall not give rise to financial gain (though it is legitimate for suppliers to levy an administrative and/or handling charge for material that has been acquired and stored in an ethical manner);
- Informed consent is required from the donor or next of kin if the donor has died whenever a new sample is taken wholly or partly for use in research;
- Patients should always be informed when material left over following diagnosis, or treatment might be used for research;
- All research using samples must be approved by the Research Ethics Committee;
- Researchers should treat all personal and medical information as confidential;

- Research participants have a right to know individual research results that affect their interests but should be able to choose whether to exercise that right. Researchers should decide at the beginning of a project what information about the results of laboratory tests done should be made available to participants and agree these plans with the Research Ethics Committee;
- Deception should only be used when absolutely necessary and should be fully explained during the Ethics application
- Records of storage and use should be properly maintained, and where necessary, linked to (or unlinked from) relevant patient information systems; with due consideration to data protection and GDPR
- All research using samples of human material, organs or tissue must be approved by a properly constituted Research Ethics Committee;
- Researchers should treat all personal and clinical information relating to research participants as confidential;
- Where possible, research participants, if they wish, should be able to know individual research results that affect their interests.

Difficult Issues Requiring Specialist Advice and Special Measures

There are some situations which raise additional ethical issues which need careful consideration. In addition, there are often different circumstances surrounding the collection of the material and the historical and legal context of the time. This has resulted in different standards guiding past practice. A further complicating feature is that it may not always be possible to know when unidentifiable material was collected.

- Samples, which have been stored for a long time may have a useful role for research, which was not, or could not be envisaged at the time the samples were collected;
- Using material for studies not specifically foreseen at the time raises difficult ethical issues;
- It is often either not possible or practical to return to donors or next of kin for new consent;
- Information obtained from research using biological samples, if disclosed, can have implications not only for the individual donor but also for their relatives, and may lead to discrimination in other aspects of their lives;
- The value of many samples is dependent upon related personal or clinical information, respect for confidentiality is therefore very important;
- Historical collections, archived or museum collections and war graves raise a number of complex issues;

- In the cases above academic staff and students are advised to seek specialist guidance.
- Academic staff engaged in forensic archaeology should also seek specialist guidance.
- Academic staff and students whose work involves the use of human tissue, organs or waste should, in addition to the TUS Postgraduate Research Regulations and the TUS Ethics Policy for Researchers, consult the Policy Statement on Ensuring Research Integrity in Ireland for guidance.

Stored Organs and Tissue

The following approach, which may offer a basis for new legislation, or a regulatory framework established as a result:

- "Valid consent may previously have been given to a particular use or uses; in which case it is lawful to use the organ or tissue as already authorised (but see third bullet point below);
- Where the donor is identifiable and unambiguous consent has not been obtained for the storage or use (or different use) of tissue, consideration should be given as to whether it is possible (or, depending on the nature of the research, necessary) to seek consent from the person concerned (or, if the person concerned is no longer alive or cannot be reasonably traced, from a relative). It is important to test assumptions about such prospects and not take for granted that organs or tissue obtained from a certain date are likely to have been "abandoned." However, logistic possibilities may sometimes have to be balanced against other factors, such as the potential distress to those who might be contacted. These are issues on which Research Ethics Committees may be able to advise;
- Where the identity of the donor is apparently unknown, or the donor cannot reasonably be traced (including where the tissue is simply too old for this to happen), there is, no prospect of obtaining contemporary consent. It is possible that a form of consent was in fact given at some time in the past (maybe orally), even if there is now no satisfactory evidence of this: and, indeed, the antiquity of some samples is such that their removal and storage would have been subject to a rather different legal and ethical framework. It would therefore be wrong to conclude that the use of unidentifiable tissue is necessarily unethical. But equally such tissue should not be used without careful consideration. The following principles should apply:

a) Tissue sample from established collections may be used for research provided that this has been approved by a local or multi-centre Research Ethics Committee and there is potential harm to the donors;
b) If there is suitable tissue for which valid consent has been given or could be obtained, this should normally be used in preference to that for which the parameters of consent are inadequately recorded;
c) Researchers should satisfy themselves that there is no evidence of samples having been obtained in an unethical manner, nor any legal or cultural objections to their use or ethical concerns about the propriety of a collection as a whole"

Confidentiality

a) When personal identifiers are used in a study, researchers should explain why this is necessary and how confidentiality will be protected.
b) Procedures for protecting the confidentiality of participants should be followed and include:
    - securing individual confidentiality statements from all research personnel;
    - coding data with numbers instead of names to protect the identity of participants;
    - using codes for identification of participants when transcribing audiotapes, and destroying the tapes on completion of transcription;
    - storing data with any identifying information in a locked file to which only one or two persons have access;
    - using pseudonyms for participants, agencies, and geographical settings in the publishing of reports;
    - disposing of information that can reveal the identity of participants or places carefully (for example, burning or shredding rather than disposal in wastebaskets).

APPENDIX 5 Additional Relevant Information Resources

All European Academies (2023). European Code of Conduct for Research Integrity.
Beauchamp TL, Childress JF. (2013) *Principles of bioethics*. 7th ed. Oxford University Press.
Bickman, L., & Rog, D. (2009). *Handbook of applied social research methods* (2nd ed., pp. 3-43). Thousand Oaks, CA: Sage
Health Service Executive (2021). National Framework for Governance, Management and Support of Health Research.
Health Information and Quality Authority (2023). The Fundamentals of Advocacy in Health and Social Care.
Health Service Executive (2021). HSE Rainbow Badge Practice Guide for Healthcare Professionals.
House of the Oireachtas (2023). *Patient Safety* (Notifiable Incidents and Open Disclosure) Act 2023.
House of the Oireachtas (2022). *Protected Disclosures* (Amendment) Act 2022.
Irish Medical Council (2024). Guide to Professional Conduct and Ethics for Registered Medical Practitioners,
Nursing and Midwifery Board of Ireland (2025). Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives.
Nursing and Midwifery Board of Ireland (2020). Guidance for Registered Nurses and Midwives on Medication Administration.
Quality and Qualifications Ireland (2021). Academic Integrity: National Principles and Lexicon of Common Terms
Resnik, D.B. (2015). What is Ethics in Research & Why is it Important?

Websites

Department of Health www.health.gov.ie
European Group on Ethics in Science and New Technologies EGE
Health Information and Quality Authority www.hiqa.ie
Health Service Executive www.hse.ie
HSE's online resource for Learning and Development www.hseland.ie
Mental Health Commission www.mhcirl.ie
Nursing and Midwifery Board of Ireland www.nmbi.ie
The Irish Statute Book database www.irishstatutebook.ie
The Irish Health Repository www.lenus.ie
Website of the Patient Safety Initiative in Ireland www.patientsafetyfirst.ie