SETU Research Ethics Committee Operations and

Application Guidance Documentation

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Contents

1. Introduction

There is a well-established acceptance of the broad principles that underlie research ethics, and SETU is committed to applying these ethical principles in its approach to research governance. In doing so SETU accepts its responsibility to the research community both within SETU, external to the SETU community, and the wider community. A rigorous and robust ethical approval process encompasses a number of themes including strong governance, clear accountability, a supported and resourced research ethical review committee (REC), accessible guidance for the SETU community, and transparency in the decision-making process. The benefits of a robust research ethical review process are manifold. They ensure validity and accuracy in data collection and its subsequent reporting. They act to protect researchers and research participants from undue external or competitive influences which may distort sound research practice. In doing so these processes will act to guarantee research outcomes, thus maximising the potential for public good.

The purposes of this document are as follows:

1.1. to lay out the operating principles of SETU REC, thus providing transparency to the SETU community;

1.2. to provide guidance to those applying for approval prior to conducting their research.

The Ethical practice of research within SETU is overseen by the SETU REC. The REC derives its authority from the office of the President, and will provide a report for information on the activities of the REC annually to both the President and the Governing Body.

2. SETU REC Operations

2.1. Membership

The committee shall be composed of at least 15 members, that provide experience in or possess an understanding of at least one of the following areas as related to research: statistics; law; and ethics. Membership should also reflect the current SETU research portfolio and the statutory or regulatory environment/framework in which such work is conducted. At least one permanent member of the REC will be external to the University and further external members will be co-opted to the committee where their expertise is required. A permanent external member provides the REC with the opportunity to consider and accommodate the views of those embedded in the region but external to the immediate SETU community. For committee members external to SETU no payment will be provided, however expenses related to meeting attendance can be reimbursed at University rates. Further specifics of the membership, e.g. term of office, can be found in the SETU REC Terms of Reference document.

2.1.1. Membership changes

To ensure that the REC expertise remains up to date and transparent in its operations, there will be an opportunity on an annual basis to review and update the membership of the committee. The benefits of this are two-fold, providing an opportunity to all members of staff to perform service to the wider SETU community and ensuring that the expertise of the REC remains relevant to SETU research portfolio and strategy. Changes in the membership of the REC will be undertaken in a cautious manner, aware of the need to retain experience and institutional memory as relates to competent REC operations. To this end no more than 10% of the membership should be changed within a single academic year.

Where new members drawn from SETU are required the REC Chair shall notify Heads of Faculty/School or Unit in the areas from which expertise is required, of this need. Heads of Faculty/School or Unit will then have the opportunity to nominate individuals for this role. Nominations of new members for the REC are subject to approval by the President.

2.1.2. Committee Chair

During the transition period, the position of committee chair, and co-chair, shall be filled from existing members of the SETU REC.

Nominations, with a first and second proposer, for the role of REC chair shall be gathered from the REC membership and these presented to the President. The chair is the appointee of the President with two nominations originating from the committee. Criteria: Knowledge of one or more of the research area(s) relevant to SETU research mission; first-hand experience of the regulatory framework governing one or more of the research areas of SETU;

2.2. Audit Function

On an annual basis the committee will perform a review and audit of applications made for ethical approval at the level of Level 8 or Level 9 (taught) programmes carried out by local ethical review committees at the School/Faculty level. Such applications will be selected from a variety of disciplines and encompass applications which were

approved, not approved, or requiring modification before further consideration. The REC will make an annual report to the President on their findings and outcomes following this.

2.3. Annual Reporting Function

The REC will report annually to the President and to Governing Body. The timing of the report will coincide with completion of the committee's business for that academic year. The report to include:

- membership of the REC;
- number of applications received;
- number of applications approved;
- number of applications refused;
- number and outcome of applications reviewed by School Ethics Committee;
- issues that arose in relation to ethical approval across the year;
- any changes to legislation or policy that needs to be incorporated.

These reports are also to be circulated to the Research Committee for information.

2.4. Meeting Operations

2.4.1. Meeting timetable.

A timetable for REC meeting throughout the year shall be decided upon prior to the commencement of the academic year. This information shall be disseminated to SETU researchers and chairs of local research ethics committees. This information will also include the final submission dates for applications that are to be considered at SETU REC. There will be a minimum of seven SETU REC meetings per year.

2.4.2. Submission of applications.

Applications for consideration by the SETU REC or triaged from the local Faculty/School committee level must be received by the secretary to the SETU REC at least twenty-eight (28) calendar days before the next proposed date, notified as above. Applications must be uploaded as a single PDF file, incorporating the application form and any supporting documents as appendices, to an online portal/intranet by this date for consideration at the next committee meeting.

2.4.3. Reviewers.

After receipt of applications, the chair, or co-chair, shall assign at two committee members as primary reviewers to assess each application, based upon the nature of the research detailed within the application and availability of committee members with the expertise necessary to perform the task. This task should be assigned to reviewers at least seven calendar days before the SETU REC meeting. Reviewers shall submit their completed review to the REC secretary report no fewer than four working days before the proposed meeting date; the review may be accompanied by a marked-up copy of the application. This will enable all committee members to prepare for REC meetings in advance, non-primary reviewers should ensure that applications are of suitable and equal quality across all research disciplines. Reviewers will present a summary of their review report to facilitate a discussion of all applications. A clear outcome decision, along with the rationale, must be recorded for each application and such as decision can only be recorded after the relevant REC meeting. Presentation of applications.

During the review process, and before the proposed REC meeting, assigned primary reviewers of a particular application may request in certain circumstances and following consultation with the chair that the applicant(s) appear before the REC and make a presentation on their application. This presentation should briefly address specific areas related to specific ethical questions identified by the reviewers. These questions, or areas requiring further clarity, must be provided to the applicant no later than four working days in advance of this meeting.

Additionally, applicants whose prior submission was subject to amendment before further consideration may be requested, by either reviewers or chair, to present before the committee on the nature of the changes made in their subsequent resubmission.

2.4.4. Guidance on making an application.

Guidance for completing the application form are provided in §7 and Appendix 2 of this document and should be considered in parallel with SETU policies on data protection, governance, and retention, and research integrity.

Updates to any guidance issued by the SETU REC on completing applications will be notified to researchers via email.

2.4.5. REC Meeting

Reviewers of applications will be required to attend the committee meeting where submissions they have reviewed are under consideration. Reviewers will be asked to present their opinion and supporting evidence in relation to each application. The chair and/or co-chair will then facilitate a discussion of the review. The committee will operate on the basis of consensus in relation to the outcome of any application. Where consensus is not achieved clarification on issues will be obtained from the applicant. The chair/co-chair is responsible for aggregating any amendments required by applicants for re-submissions of their application. The outcome of the REC in relation to applications can be one of the following:

1. Approve;
2. Request amendment subject to desk review;

3. Request amendment subject to committee review;
4. Decline.

The REC decision in relation to their submission shall be communicated to the applicant by email within four working days of the REC meeting. Members of the REC shall be informed of the outcomes of all applications and any requested amendments. The details of requested amendments requested by the REC, following consideration of an application, will be provided to applicants. Applicants they will be informed whether these amendments are subject to desk review or committee review. Where a desk-review is required for amendments the details of the requested amendments, applicants response, and the reviewers decision will be circulated to all REC members. The original reviewers will confirm whether they are satisfied with the presented amendments via email communication to the chair/co-chair. In addition, they will also be informed as to whether they are required, or not to present these amendments before the REC.

2.5. Local Ethical Review Processes

Prior to application for approval by SETU REC all research activity undertaken within a L8, L9 Taught, L9 Research, and L10 programme must in the first instance be triaged and/or reviewed by a local research ethics review body (L-REB). In all instances it would be expected that research activity undertaken at L8 and the majority of research activity within L9 Taught programmes would receive sufficient ethical consideration and review from a local research ethics review body.

A local research ethics review body may be a sub-group of the Research Programme Board or Programme Board relevant to a particular educational programme or a separate ethical review body within an academic unit.

Bodies responsible for local research ethics decision should direct students concerned to complete an ethics triage checklist for all programmes or projects arising within particular programmes before submission for review or approval. If after review of the completed ethics triage checklist the L-REB requires further information students will be directed to complete the SETU REC application form and submit this to their L-REB . Following submission and review a student may record their proposed research activity as having received approval from their L-REB or notification that an application must be submitted to the SETU REC for review prior to commencing work. This will provide a record that can be reviewed locally and by the SETU REC retrospectively. This will also enable clear decision making in the cases of L9 and L10 applications that are referred to the SETU REC. Please also refer to §6.

2.6. Appeal of REC Decisions

2.6.1 Appeals of SETU REC decisions

Appeals of decisions related to the outcome of applications may be classified as stage one or stage two appeals. Note that dissatisfaction with the outcome of an application to the REC is not grounds for an appeal.

2.6.1.1 Stage One Appeal

A stage one appeal shall involve the applicant directly contacting the SETU REC chair to lodge an appeal of the decision where SETU REC declined to approve an application. The REC Chair may consult with individuals with discipline-specific expertise, excluding the original reviewers,

Where the SETU REC chair declines to uphold a stage one appeal an applicant may on the ground of procedural error make an appeal to the Office of the President of SETU.

2.6.1.2 Stage Two Appeal

In circumstances where the applicant is dissatisfied with the outcome of the stage one process, they may make further appeal to the Office of the President who will appoint an independent panel of two senior researchers or discipline expert members of staff not associated with the SETU REC to review the compliant.

The panel will be established within 10 working days of receipt of the appeal.

The panel will furnish a written report detailing their decision within 10 working days of their appointment and this decision will be communicated to the appellant and Chairperson of the REC within five working days of receipt of the report.

2.6.2 Appeal of local Faculty/School ethics committee decisions

If a local Faculty/School ethics committee declines to approve an application, an appeal may be made to the SETU REC in accordance as specified in §2.5.4.2. An appeal may only be made in relation to outcome four as specified under section 2.4.5. An appeal should be submitted within five working days of receipt of the written decision related to the application.

Note that dissatisfaction with the outcome of an application to the REC is not grounds for an appeal.

In the case of a local Faculty/School ethics committee, the appeal should, in the first instance, be sent to the relevant Head of Faculty/School who must then forward it to the Chairperson of the SETU REC within five working days.

The Chair of the SETU REC will nominate two members of the SETU REC, independent of the Faculty/School from which the appeal arises, to review the appeal within 10 working days.

The decision of the review will be communicated in writing within 10 working days of receipt of the complaint. The decision of the Appeals Panel is final.

3. Guiding Principles

In this section we establish and make apparent the principles under which research ethics decision making is carried out. Members of the SETU community engaged in research must apply an ethical approach and consider the four pillars of ethical research, described below, to all stages of their research no matter when an SETU researcher is involved. For the purposes of this policy and all associated documentation we consider research as being broken into 4 distinct stages including: collection of data; use/analysis of data; management of data; and storage of data. The information provided below should be used by all researchers when making an application for approval to conduct research.

Dependent on the nature of the research and where appropriate an ethical approach to conducting research would consider a number of values. These include a commitment to the welfare, protection and safety of human and animal participants. A duty to respect the statutory rights and when appropriate wishes of all involved. A responsibility to conduct the highest possible quality research, and to communicate the outcomes of this research to relevant stakeholders and policy-makers in an appropriate fashion and timely manner. Researchers are obliged to consider who benefits from any research conducted and who must bear its burdens.

3.1. The Four Pillars of Ethical Research

Whether conducting research involving the reuse of data or the gathering of primary data from work involving animal or human participants, all researchers must be cognisant of the four pillars of ethical research. The four pillars of ethical research are as follows:

- Respect for the Dignity of the participant
- Voluntary Informed Consent
- Minimising Risk of Harm
- Confidentiality

In any application for research ethics approval, researchers must be able to demonstrate that they have considered the four pillars of ethical research.

3.1.1. Respect for the Dignity of the Participant

Researchers must operate within an ethic of respect for any participant involved in the research they are undertaking. This applies to both human and animal participants involved directly or indirectly. The ethic of respect also extends to the researchers themselves.

Researchers should ensure that considering the scope and objectives of the proposed research, the process of selection, exclusion and inclusion of categories of research participants is fair and robust. All details of this process must be accurately described in both the research proposal and the results of the research.

Participants should be treated fairly, sensitively, with dignity, and within an ethic of respect and freedom from prejudice regardless of any inherent or individual characteristic. Researchers should avoid using designations that could give rise to unreasonable generalisation, resulting in possible stigmatisation of any group of participants. Research making use of material that is derived from human or animal donors must always be aware of and respectful of the dignity of human or animal donors, and where appropriate animal owners involved in the process.

Specifically, for research where human participants are involved, consideration must be made throughout the process to the capacity of human beings to make their own decisions.

Where human participants are unable to make their own decisions or have diminished capacity to do so, respect for them involves empowering them where possible and providing for their protection as necessary. Categories of otherwise qualified participants for a research project should not therefore be excluded merely because of their vulnerability or diminished capacity. With regard specifically to human participants no unfair burden of participation in research should be placed on particular groups

As per the mission of SETU, this value also requires that there is fair access to the benefits of the research and that the research outcomes should be made accessible to research participants in a way that is timely and clear.

3.1.2. Voluntary Informed Consent

Where appropriate researchers are required to obtain informed consent from all participants in a voluntarily manner. This entails all participants in the proposed research being made fully aware of the aims of the research. Where research involves privately-owned animal participants researchers must obtain consent of the owner in an appropriate fashion.
Prior to obtaining informed consent, researchers must provide a clear and detailed information leaflet the details of their research to participants prior to receiving consent and commencing the research. For detail of what should be included refer to Annex 1.

IT IS ESSENTIAL TO OBTAIN INFORMED CONSENT BEFORE COMMENCING ANY RESEARCH STUDY.

Researchers engaged in 'Health Research' must be particularly aware of their responsibilities regarding informed consent as a consequence of the GDPR 2016 and the Health Research Regulations 2018[1] which apply to all forms of health research (which is broadly defined) and came into legal effect on 8th August 2018. These place additional requirements for securing informed consent and data protection compliance over and above the general requirements contained in the GDPR.[2]
As research is usually an iterative process, circumstances may evolve to an extent where fresh/revised consent may become necessary. Researchers must also be aware of the aspects below as they relate to informed consent.

Participation is voluntary:
This requires that all participants freely choose to participate without being subject to any duress or pressure either prior to or during the research in question. Where animal participants are involved in a study, their early removal from a study is at the request of their owner.
Right to Withdraw:
It follows that researchers must recognise the right of any participant to withdraw from the research for any or no reason, and at any time, and participants must be informed of this right from the outset. The procedure by which consent may be withdrawn must be provided to participants at the time of obtaining consent.
Incentives:
Use of conditional incentives upon participation (e.g. payment or a donation to charitable) in research may be problematic as i) it may put potential participants under implied pressure to participate and ii) the potential to create a bias in

[1] S.I. 314 of 2018 DATA PROTECTION ACT 2018 (SECTION 36(2)) (HEALTH RESEARCH) REGULATIONS 2018
[2] See Department of Health Guidance Document October 2018 https://www.hrb.ie/fileadmin/1._Nonplugin_related_files/RSF_files/GDPR_guidance_for_researchers/Health_Research_Informati on_Principles.pdf
More generally, see Health Research Board website: https://www.hrb.ie/funding/gdpr-guidance-for-researchers/

sampling or in participant responses. Consequently, it is recommended that researchers avoid the use of incentives to encourage participation. Where applicants propose to utilise incentives, e.g. reimbursement of expenses, justification, and appropriate mitigations, must be detailed in the application. Researchers may seek further advice from the Chair of the Research Ethics Committee.

3.1.3. Minimising Risk of Harm

As a principle of all research participants should not be exposed to risks greater than or additional to those normally encountered.

Researchers must pay attention, in both their application and conduct of their work, to the risk of harm to participants and ensure that such risk is minimised. Researchers are advised to consider carefully the various types of harm that participants could potentially be exposed to either during, or as a consequence of, any particular research activity. Researchers should also consider carefully minor discomfort, physical or otherwise, that can occur in the course of data gathering (e.g. interview or blood pressure measurements).

Researchers must make known to the participants (or their guardians or responsible individuals) any predictable harm that could arise from the process or findings of the research. Any unexpected harm, which arises during the research, must be brought immediately to their attention or to the attention of their guardians or responsible others as appropriate. Where risk to participants does exist, researchers must ensure that adequate supports are available for participants to minimise any such risk. This must be communicated to participants, guardians, or responsible individuals.

Researchers must take steps to minimise the effects of designs that advantage or are perceived to advantage one group of participants over others. If researchers find during experimental design that their intervention is having perceived benefits and positive effects on participants over the control or comparison group, it is the obligation of the researcher to make these benefits available to the comparison group.

Research involving animal study participants must adhere to all welfare stipulations and procedural refinements required by any external statutory instrument governing the work.

3.1.4. Protecting Privacy and Confidentiality

Researchers must ensure that adequate safeguards are in place to protect the privacy of participants, or in the case of animal participants their owners, and the confidentiality of personal data gathered in the course of any research. The mechanism by which this happens must be detailed in any application for research ethics approval. Researchers are advised to consider, where appropriate, the following headings in the course of their application.

Privacy

Researchers must recognise the participants' entitlement to privacy and must accord them their rights to confidentiality and anonymity, unless they or their guardians or responsible others, specifically and willingly waive that right. In such circumstances it is a requirement that the researcher obtains such a waiver in writing. Conversely, researchers must also recognise participants' rights to be identified with any publication of their original works or other inputs, if they so wish. In some contexts researchers should be aware that it may be the expectation of participants to be so identified.

Limits on Confidentiality - Disclosure

Certain categories of research, by their nature, may involve potential limits being placed on confidentiality (e.g. the need to report possible criminal conduct to relevant bodies/ authorities). In such cases, the researcher must inform all participants of this possibility in the Participant Information Sheet and research should only proceed once the consent of the participant to this has been obtained.

In other cases, researchers may judge that the effect of the agreements they have made with participants, on confidentiality and anonymity, will allow the continuation of illegal behaviour, that comes to light in the course of the research. In such circumstances they must carefully consider making disclosure to the appropriate authorities. If the behaviour is likely to be harmful to the participants or to others, the researchers must also consider disclosure. Insofar as it does not undermine or obviate the disclosure, researchers must apprise the participants or their guardians or responsible others of their intentions and reasons for disclosure.

At all times the decision to override agreements on confidentiality and anonymity must be taken after careful and thorough deliberation. In such circumstances it is in the researchers' interests to make contemporaneous notes on decisions and the reasoning behind them, in case a misconduct complaint or other serious consequence arises. The researcher may also seek guidance from the chair of the SETU Research Ethics Committee.

Researchers should also debrief participants at the conclusion of the research and to provide them with copies of any reports or other publications arising from their participation. If formal reports or publications are the sole research output arising from the study, applicants must endeavour to ensure an "accessible" or lay summary of the outcomes are made available to all participants. Where the scale of the research makes such a consideration impractical, alternative means of communication should be used to ensure participants are informed of the outcomes.

Where research involves privately owned animal participants, there is a similar expectation that a debriefing process will be in place to inform owners of research outcomes.

Data Protection

Researchers must comply with the legal requirements in relation to the storage and use of personal data as set down by the EU General Data Protection Regulation (GDPR) 2016 and the Data Protection Acts 1988-2018 and any subsequent applicable legislation. Researchers must also consult and comply with the provisions of SETU Data Protection Policy.

In essence participants in research are entitled to know how and why their personal data is being stored, to what uses it is being put and to whom it may be made available. Details to be shared with participants in information sheets are provided in Annex XX.

Researchers must also have participants' permission to disclose personal information to third parties and are required to ensure that such parties are permitted to have access to the information. Researchers are also required independently to confirm the identity of such third parties and must keep a record of any disclosures. Disclosure may be written, electronic, verbal or any visual means.

Data obtained from participants must be kept safe and secure. To this end, electronic data should always be stored on secure servers and NOT on portable storage devices (e.g. usb flashdrives, memory cards, laptops, video recorders, phones etc.). Where portable storage devices are used for initial collection of data, these data should be transferred to a secure server and deleted from the portable storage device as soon as possible. Researchers must demonstrate their adherence to the above guidance in the course of their application.

The GDPR and Data Protection Acts also give private citizens the right of access to any personal data that is stored in relation to them. Researchers seeking to exploit legal exclusions to such right must have a clear justification for so doing, please see Annex XX for specific conditions.

4. Types of Research requiring approval

Any research activity in the areas below conducted by a member of SETU community must receive approval before beginning. The areas of research requiring approval include, but are not limited to, the following:

- Human experimentation;
- Animal experimentation;
- Ionizing radiation;
- Collecting of sensitive or confidential data;
- Research that involves people's personal information, rights or freedoms (this includes internet-based research)
- Children and young people or any vulnerable groups (examples of vulnerable groups might include, but are not limited to: ; prisoners; refugees; those in care; addiction service users; adults with a learning disability or cognitive impairment; individuals with mental illness or other serious illness/life-limiting conditions; individuals with conditions which may have social or legal stigma over researched groups)
- Research that involves SETU staff or SETU students as research subjects;
- Research where there may be a potential for subjects to feel under pressure to participate;
- Research that may involve a risk of harm (physical, social, economic, legal or other) to the researcher;
- Research which may lead to the disclosure of acts on the part of subjects, either consciously or unconsciously, that are professionally or morally disapproved of or are against the law;
- Research that involves a potential stress or loss to subjects (psychological, physical, economic, reputational) beyond those of everyday life if the subjects had not participated in the study;
- Research involving direct observations of people's activities (either open or covert observation).
- Research involving human or animal remains, cadavers, tissues, biological fluids, embryos or foetuses;
- Research involving manipulation or induction of a change in the environment;
- Research involving secondary use of data (use of data initially collected for another purpose) - health records; employee records; student records; computer listings; banked tissue - if any form of identifier is involved or if private information pertaining to individuals is involved;
- Research on sensitive topics;
- Research where a gatekeeper is involved;
- Research using the internet or social media;

- Research involving artificial intelligence;
- Use of financial incentives/inducements;
- Use of any substance or equipment that may pose an excessive risk to human health.

5. Stakeholders

When considering applying for ethical approval researchers must consider the individuals or groups of individuals that may be impacted, positively or negatively, by their proposed research. These may be directly involved in the research activity or encompass those indirectly impacted by the outcomes or conduct of the research activity itself.

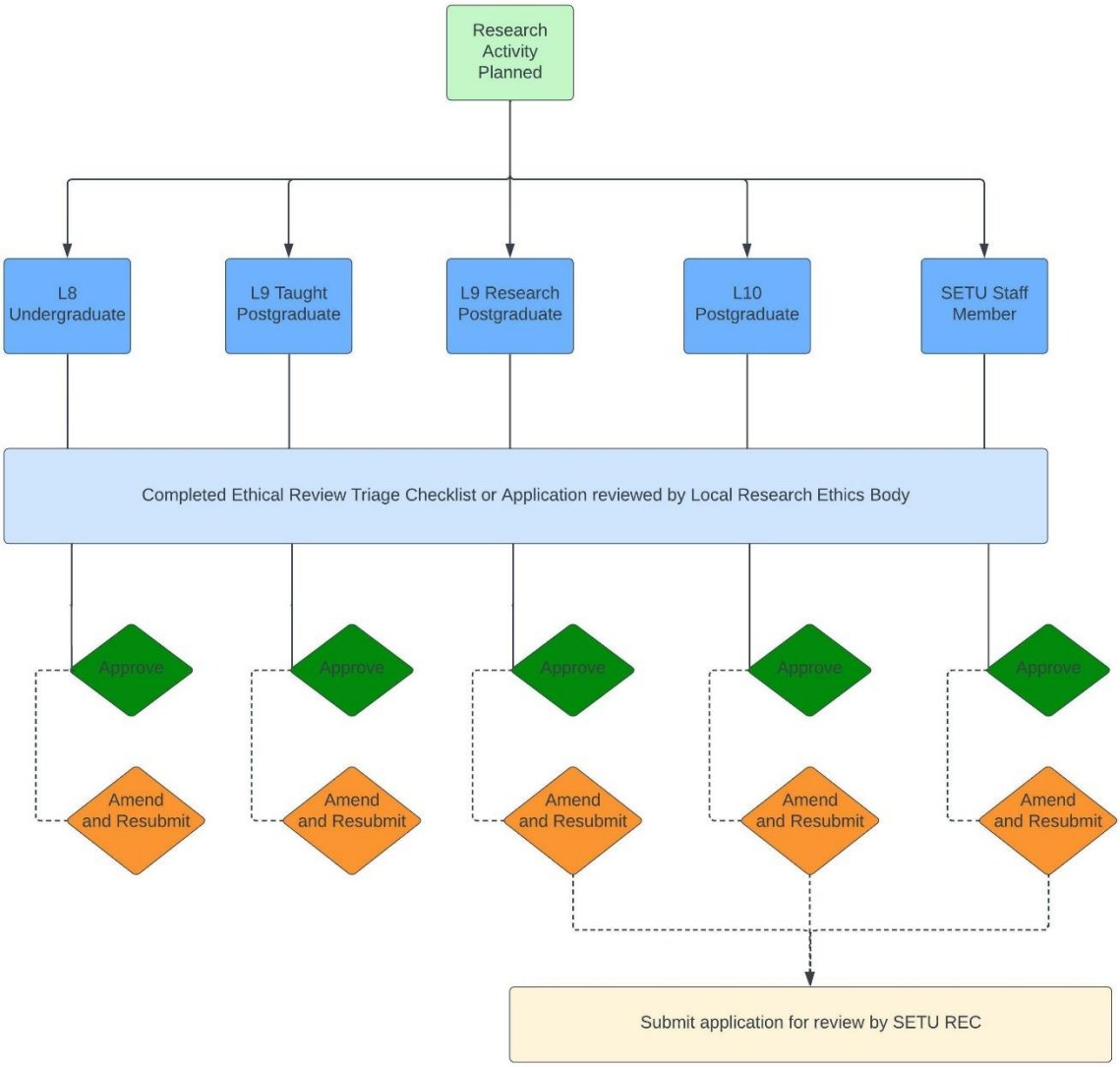
These stakeholders may include, but are not limited, to the following:

- Immediate research colleagues;
- The SETU community;
- Research participants;
- Carers or guardians of research participants;
- Groups of individuals categorised by particular demographic characteristic(s);
- Owner of, or responsible individual for, animal(s) involved in research activity;
- The intended user group(s) of any tool or output produced.

As a first step researchers must consider the risk of harm and what potential benefits may accrue to all stakeholders impacted by their proposed research. Furthermore, researchers must outline the mechanisms that will be put in place to minimise or prevent any negative impact that may occur.

6. Route to Research Ethics Application

All researchers must notify, and seek approval from, their Research Programme Board, their local School/Faculty research ethics committee or SETU research ethics committee prior to commencing any research work. The decision tree below indicates the likely route for research ethical approval dependent on a researcher's position or programme of study.



7. Application Form & Requirements

Appendix 1. Information Letter/ Study Invite

Annex A. Template Letter

Instructions: Researchers can edit the template text below to construct an information letter/invite that will be provided to participants in their proposed study. This must be submitted along with their application for research ethics approval.

DATE:

TITLE OF RESEARCH STUDY

(The title may need to be shortened. The title does not have to appear in a cover letter, but it should appear at the beginning of any questionnaire.)

Overview

You are being invited to participate in a study *[provide further explanation/alternative title]* as part of a research study about *[explain the study's purpose in a few words.]* This study is being conducted by [*insert name of Researcher/ Researchers (including job title) and name of Research Supervisor (if Researcher is a learner)],* from the [*insert department/school affiliation]* at South East Technological University (herein referred to as SETU).

[*Researcher should then indicate the overall context of the research e.g. as part of an undergraduate project, graduate learner project, thesis, dissertation, national or international collaborative project/initiative etc. If funded, identify the funding agency.*]

Why have you been approached to participate?

You have been identified as a possible participant in this study because [*explain succinctly and simply why the prospective subject is eligible to participate, if applicable*.]

What are you being asked to do?

You are being asked to participate in a *study/survey/trial* on *[briefly set out the goal of the survey/study*]. You will be asked *[set out the details of the study, e.g. number of questions and type e.g. closed ended/open ended etc. You are free not to answer any particular question you do not wish to answer for any reason].* The study should take about *[indicate approximate amount of time]* to complete.

Do you have to participate?

Your participation in this survey/study is entirely voluntary.

[Optional statement should study involve students of SETU]. Where the researcher is your lecturer/tutor/supervisor, you should not feel obliged to participate by that fact. There will be no negative consequence for your learning and assessment should you decide not to participate.

By completing and submitting the survey OR consenting to the study, you are voluntarily agreeing to participate. Furthermore, you have the right to withdraw from this survey/study at any stage of the research and you can do so by *[applicant must provide mechanism].*

What are the benefits of you participating?

The information collected may not benefit you directly, but the information learned in this study should provide more general benefits *[if possible, provide summary of the expected benefits to be derived from the survey/study]*

What are the risks of participating in this survey?

Generally, there are minimal risks to participants in this type of research study and methodology.

This survey is anonymous. Do not write your name on the survey. *[If this is a web-based survey, indicate how you will provide anonymity (e.g., not collect addresses or other identifiers which alone or by cross reference with other data would identify the respondent). Also, indicate the particular survey tool being used e.g. Qualtrics/surveymonkey etc. but that absolute anonymity cannot be guaranteed over the Internet.]* No one will be able to identify you or your answers, and no one will know whether or not you participated in the study. Individuals from *[give name of the funding agency, if any,]* and the Institutional Review Board may inspect these records. Should the data be published, no individual identifying information will be disclosed.

OR

What are the risks of participating in this study?

Generally, there are minimal risks to participants in this type of research study and methodology. *[Please detail the mechanisms in place to identify potential risks/harm and mitigations to offset these].*

Any personal data collected during the course of this study will be treated confidentially and in accordance with SETU policies on data protection, governance and retention. *[Please provide details of the practical measures the researcher will take to ensure data is correctly stored, for what period and under what conditions. State who will have access].* No one will be able to identify you or your answers, and no one will know whether or not you participated in the study. Individuals from *[give name of the funding agency, if any,]* and the SETU Research Ethics Committee may inspect these records. Should the data be published, no individual identifying information will be disclosed.

There are no costs to you for participating in the study.

[If researcher is of the opinion that questions asked could raise a risk to the health and/or well-being of participants, the following statement should be included]

Risk to the health and well-being of participants is generally very low in this type of study. However, should you experience upset or distress by participating in this survey, you should seek immediate assistance from a relevant professional/service provider *[provide list of relevant support services and contact details as appropriate].*

How will the information you provide be used?

The information you provide will *[provide a brief but clear statement of expected actual and potential uses of data collected (including use in further studies, publications etc.)].*

If you want to know more?

If you have any questions about the study, please contact *[Name, mailing address, phone number, and email address of the Researcher (and supervisor if Researcher is a learner).]* This study is being carried out in accordance with SETU Research Ethics Policy and Guidelines following review and approval. If you have any concerns about your rights in this study, please contact the Chair of the Research Ethics Committee at ethics@setu.ie.

Annex B. Information Letter/ Study Invite Checklist

- What exactly the research involves (i.e. purpose and methodology);
- What the participants will be expected to do during the research process (including all known risks however slight associated with their participation);
- The full set of inclusionary and exclusionary criteria for participation in the research
- What measures will be put in place to deal with any potential risks to participants;
- That a Research Risk Assessment Form is available to be viewed by participants if they so choose;
- If the research involves the taking of samples (e.g. blood, tissue etc.), how those samples will be taken, how they will be stored and how and when they will be disposed of.
- The expected benefit/s of the research;
- For what purpose/ purposes the data provided by them will be used;
- Confirmation that the data relating to each participant will be kept only for the purpose/ purposes specified (and that it may be included in future publications where that possibility is envisaged by the researcher);
- Confirmation that data collected will be securely stored and electronic material will be password protected;
- Who will have access to the data and why;
- Specification of any person who provides funding for, or otherwise supports, the project and any direct or indirect access that person will have to the personal data collected –this is particularly relevant to any commercial involvement with the research and/or the researcher
- That all data relating to participants will be kept confidential and anonymity of participants will be preserved (apart from situations where limits of confidentiality and anonymity may apply);
- That any potential limits on confidentiality have been properly explained – (for example in circumstances where information is provided by a participant which must be disclosed to the Gardai and/ or other relevant authorities or where material is subject to a court order/ judicial ruling);
- How long the data will be retained by researcher;
- How the data will be disposed of (so as to preserve confidentiality);
- Confirmation that an assessment of the data protection implications of the research has been carried out and an indication of the level of risk identified by such
- That participation is entirely voluntary and that participants have a right to a ‘cooling off period’ (where reasonably practicable) entitling them to a change of mind before commencing participation.
- That participants are otherwise free to withdraw from the research at any time.
- That feedback on research findings will be made available to participants and how this will be achieved.

- Whether the research findings will be used or disclosed for commercial purposes
- [In cases of L9R and L10R] Date ethical approval/clearance was granted for the research by the SETU REC and contact details for the committee.

Appendix 2. GDPR Guidance

Researchers must comply with the legal requirements in relation to the storage and use of personal data as set down by the EU General Data Protection Regulation (GDPR) 2016 and the Data Protection Acts 1988-2018 and any subsequent applicable legislation. Researchers must also consult and comply with the provisions of the SETU Data Protection Policy.

In essence participants in research are entitled to know how and why their personal data is being stored, to what uses it is being put and to whom it may be made available.

In the Information Sheet provided to participants, the following details should be addressed:

- That the data relating to each participant will be kept only for the purpose specified, will be relevant to the research and not excessive;
- How the data will be kept safe and secure e.g. if in manual form, where will the data be stored and how. If electronic information that it is password protected, encrypted as appropriate;
- If the information is to be seen and/or used by persons other than the researcher, who will that be and why;
- How long the information will be retained for;
- How the data will be disposed of/ destroyed;
- Confirmation that an assessment of data protection implications of the research has been carried out as well as the level of risk identified;
- Any plans to use the data in future studies, research or publications.

Researchers must also have participants' explicit permission to disclose personal information to third parties and are required to ensure that such parties are permitted to have access to the information. Researchers are also required independently to confirm the identity of such third parties and must keep a record of any disclosures. Disclosure may be written, electronic, verbal or any visual means.

Personal data of participants must be kept safe and secure. To this end, electronic data should always be stored on secure servers and NOT on portable storage devices (e.g. USB flashdrives, memory cards, laptops, video recorders, phones etc.). Where portable storage devices are used for initial collection of data, these data should be transferred to a secure server and deleted from the portable storage device as soon as possible.

The GDPR and Data Protection Acts also give private citizens the right of access to any personal data that is stored in relation to them. Researchers seeking to exploit legal exclusions to such right must have a clear justification for so doing.

An inherent part of ethical research is that an assessment of risks to data protection is carried out prior to commencement of the research. At a minimum, this assessment should include:

- a description of the envisaged processing operations and the purposes of the processing
- an assessment of the necessity and proportionality of the processing
- an assessment of the risks to the rights and freedoms of data subjects
- the measures envisaged to address the risks and to demonstrate compliance with legal requirements.[14]

Participants should be informed that this assessment has been carried out as well as the level of potential risk identified.
In certain cases, a formal **Data Protection Impact Assessment ("DPIA")** may be required by law (Appendix 3). In such case, the DPIA shall be completed and documented in accordance with the provisions of the SETU DPIA Policy and Procedures.

Appendix 3: Data Protection Impact Assessment Template

Background:
Data Protection Impact Assessments ('DPIAs') can be used to identify and mitigate against any data protection related risks arising from a new project, which may affect SETU. DPIAs are mandatory for any new high risk processing projects.

When to use a DPIA:
Under the GDPR, a DPIA is mandatory where data processing "is likely to result in a high risk to the rights and freedoms of data subjects (the person to which the data relates). Conduct of a DPIA is mandatory as part of this application process at SETU and will serve as a useful tool to help comply with data protection law. The DPIA should be carried out prior to the processing of data and a copy sent to the Data Protection Coordinator to retain on file.

Who must carry out the DPIA:
It is the responsibility of the project team to ensure that a DPIA is carried out for any new data processing projects.

DPIA Process:

1. **Need for DPIA:**
   Summarise the need for a DPIA

2. **Describe the information flows:**
   Describe the collection, use and deletion of personal data here and it may also be useful to refer to a flow diagram or another way of explaining data flows. You should also say how many individuals are likely to be affected by the project.

3. **Identify data protection and related risks**
   Identify the key privacy risks and the associated compliance and corporate risks.

4. **Identifying data protection solutions to reduce or eliminate the risks**
   Describe the actions you could take to reduce the risks, and any future steps which would be necessary.

5. **Signing off on the outcomes of the DPIA**
   Ensure appropriate sign off of outcomes is formally documented and retained.

6. **Integrating data protection solutions into the project**
   Ensure the controls and actions identified are tracked through to completion to ensure the rights of the data subject are upheld.

Template

1. Need for a DPIA Please answer the below questions	
Will the project involve the collection of new information about individuals?	
Will the project compel individuals to provide information about themselves?	
Will information about individuals be disclosed to organisations or people who have not previously had routine access to the information?	
Are you using information about individuals for a purpose it is not currently used or in a way it is not currently used?	
Does the project involve you using new technology that might be perceived as being privacy intrusive? For example, the use of biometrics or facial recognition.	
Will the project result in you making decisions or taking action against individuals in ways that can have a significant impact on them?	
Is the information about individuals of a kind particularly likely to raise privacy concerns or expectations? For example, health records, criminal records or other information that people would consider to be private.	
Will the project require you to contact individuals in ways that they may find intrusive?	

2. Describe the information flows

Date of Assessment:	
Assessment performed by:	
Function/Department:	
Process Name:	
Description of the envisaged processing operations: (Including collection, deletion and use)	
Purposes of the processing:	
Legal basis for processing:	
Necessity of the processing (Justification)	
Proportionality of the processing (Estimated number of Data Subjects Affected)	
Individuals consulted during the performance of DPIA (Include internal and external consultations held)	

3. Identify data protection and related risks	**4. Identifying data protection solutions to reduce or eliminate the risks**

No.	Privacy Issue	Risk	Existing Controls Identified	Risk Rating L x I	Additional Controls/ Actions Required	Action Owner	Deadline Date
1							

5. Signing off on the outcomes of the DPIA	
DPIA Assessment result: (Pass- risk eliminated, avoided or accepted; Fail- risk un-avoided)	
Approved by:	

6. Integrating data protection solutions into the project	
Next steps/Actions	

Guidance

Example Risks to Individuals:

- Inappropriate disclosure of personal data internally due to a lack of appropriate controls being in place.
- Accidental loss of electronic equipment may lead to risk of disclosure of personal information to third parties.
- Breach of data held electronically by “hackers”.
- Vulnerable individuals or individuals about whom sensitive data is kept might be affected to a very high degree by inappropriate disclosure of personal data.
- Information released in anonymised form might lead to disclosure of personal data if anonymisation techniques chosen turn out not to be effective.
- Personal data being used in a manner not anticipated by data subjects due to an evolution in the nature of the project.
- Personal data being used for purposes not expected by data subjects due to failure to explain effectively how their data would be used.
- Personal data being used for automated decision making may be seen as excessively intrusive.
- Merging of datasets may result in a data controller having far more information about individuals than anticipated by the individuals.
- Merging of datasets may inadvertently allow individuals to be identified from anonymised data.
- Use of technology capable of making visual or audio recordings may be unacceptably intrusive.
- Collection of data containing identifiers may prevent users from using a service anonymously.
- Data may be kept longer than required in the absence of appropriate policies.
- Data unnecessary for the project may be collected if appropriate policies not in place, leading to unnecessary risks.
- Data may be transferred to countries with inadequate data protection regimes.

Corporate Risks:

- Failure to comply with the GDPR may result in investigation, administrative fines, prosecution, or other sanctions. Failure to adequately conduct a DPIA where appropriate can itself be a breach of the GDPR.
- Data breaches or failure to live up to customer expectations regarding privacy and personal data are likely to cause reputational risk.
- Public distrust of organisation’s use of personal information may lead to a reluctance on the part of individuals to deal with the organisation.
- Problems with project design identified late in the design process, or after completion, may be expensive and cumbersome to fix.
- Failure to manage how your company keeps and uses information can lead to inefficient duplication, or the expensive collection and storage of unnecessary information. Unnecessary processing and retention of information can also leave you at risk of non-compliance with the GDPR.
- Any harm caused to individuals by reason of mishandling of personal data may lead to claims for compensation against the organisation. Under the GDPR the organisation may also be liable for non-material damage.

Compliance Risks:

The organisation may face risks of prosecution, significant financial penalties, or reputational damage if it fails to comply with the GDPR. Individuals affected by a breach of the GDPR can seek compensation for both material and non-material damage.

Failure to carry out a DPIA where appropriate is itself a breach of the legislation, as well as a lost opportunity to identify and mitigate against the future compliance risks a new project may bring.

Examples of data protection solutions:

- Deciding not to collect or store particular types of information.
- Putting in place strict retention periods, designed to minimise the length of time that personal data is retained.
- Reviewing physical and/or IT security in your organisation or for a particular project team and making appropriate improvements where necessary.
- Conducting general or project-specific training to ensure that personal data is handled securely.
- Creating protocols for information handling within the project, and ensuring that all relevant staff are trained in operating under the protocol.
- Producing guidance for staff as reference point in the event of any uncertainty relating to the handling of information.
- Assessing the need for new IT systems to safely process and store the data, and providing staff with training in any new system adopted.
- Assessing the portability of using anonymised or pseudonymised data as part of the project to reduce identification risks, and developing an appropriate anonymisation protocol if the use of anonymised data is suitable.
- Ensuring that individuals are fully informed about how their information will be used.
- Providing a contact point for individuals to raise any concerns they may have with the organisation.
- If using external data processors, selecting appropriately experienced data processors and putting in place legal arrangements to ensure compliance with data protection legislation.
- Deciding not to proceed with a particular element of a project if the data privacy risks associated with it are inescapable and the benefits expected from this part of the project cannot justify those risks.

Risk Assessment Guidance:

Likelihood/Potential for an Incident to occur	Impact/Outcome of Incident	Risk Level Calculation L X I	Guideline Action Timetable

1 - Rare: No history of event occurring over period of years. This event may occur but in exceptional circumstances.	**1.** Minor compromise of privacy (e.g. un-sensitive personal data such as helpdesk ticket compromised)	1 – 2 Acceptable	No Action
2 - Unlikely: The event would be expected to occur annually	**2.** Minor data breach (e.g. inappropriate contact of data subject via email)	3 – 5 Low	Prioritise after medium risk actions complete
3 - Possible: This could occur monthly, as such it has a reasonable chance of occurring.	**3.** Moderate data breach (Sensitive data e.g. payroll compromised)	6 – 10 Medium	Prioritise after high risk actions complete
4 - Likely: Expected to occur at least weekly, the event will occur in most situations	**4.** Significant data breach (Financial loss, severe stress for a data subject or data subjects	11 – 15 High	Prioritise Action as soon as Practical
5 - Certain: Expected to occur almost daily, it is more likely to occur than not.	**5.** Major data breach (Risk of severe financial loss to a large number of data subjects)	16 – 25 Very High	Action Urgent