Guidance for using the Research Ethics Application Management System (REAMS)

Trinity College Dublin

Contents

Introduction

This document is designed to provide guidance when using the Research Ethics Administration Management System (REAMS) to apply for Ethical Approval. Research undertaken by Trinity staff or students, which involves animals, humans, or human data (excluding archival data) requires ethical approval from Trinity. This includes research that has ethical approval from other agencies or institutions, the only exception being projects approved by the Joint Research Ethics Committee (James & Tallaght Hospitals) (JREC). Ethical approval is not granted retrospectively. Applications will be subject to review of all potential ethical issues extending over the lifetime of the project – including the entire period during which data are retained. Applications will also be reviewed in respect of any data protection issues that may arise during the conduct of the project.

This guidance document is provided to assist the development of robust ethics applications. The following section provides a list of the common abbreviations used throughout this document. There is then an overview of important steps that must be taken when preparing an application for ethical approval. Finally, there are sections that concern the routing of applications to the appropriate reviewing bodies, and the process of review. Based on responses to some of the answers in the ethics application, the REAMS system will automatically direct applications to the appropriate Research

Ethics Committee (REC), provide a determination of the level of risk associated with the project, and specify the nature of the review process that is required (i.e., supervisor, expedited, or committee review).

The purpose of this guidance document is to support ethics applications concerning projects that involve human participants or human data and pertaining to ethics applications in animal and ecology. In the case of projects that involve both animal and human participants, two separate applications are required.

In vitro research on cell lines, microorganisms, or non-biological materials *that does not* extract primary biological material from humans or animals or that is not tested on humans or animals are not currently required to seek ethics approval from a Trinity research ethics committee. Researchers should, however, determine the local licences and permissions that are required.

The bulk of this document concerns the Ethics application form and its subsections. There are eleven subsections, some of which must be completed for all applications (mandatory), and some of which will appear for only some applications depending on their characteristics (dependent).

Table 1: Summary of the Ethics Application Form

Mandatory Sections for all applications	**Notes**
Applicant & Collaborator	Specifies the applicant and any collaborators – including Trinity Principal Investigator (PI) or supervisor.
Project Details	Describes the project aims and objectives, the methodologies to be used, and identifies characteristics that determine the dependent sections to be completed.
Risk	Requires applicants to consider a broad range of risks that may arise from the research.
Declarations	All student applications require signoff and approval from a supervisor before submission. Any applications not prepared by the nominated PI will also require PI signoff and approval prior to submission

Dependent Sections	Notes
Sampling & Recruitment	Only required if project data are to be collected from primary sources
Data Protection	Required if the Research Data being processed, could directly or indirectly identify a living individual
Animal Research	Required for projects involving invertebrate animals in a laboratory, or data derived from any animals in the wild
Health related Research	Only required if the project is Health Research as defined in the Health Research Regulations
Consent	Required if the project requires consent or assent from participants
Funding	Only required if the project is funded. Funding is usually in the form of a grant.
Human Biological Samples	Only required if the research project utilises human biological samples

This guidance document includes information that in the first instance is generalisable across all the disciplines in Trinity. It does not purport to represent the gold standard definitions or replace academic texts. It provides the information needed to complete an ethics application. In the application form, information supporting the completion of individual sections/ subsections is available in the following formats.

1. **Help Text:** Appears in the user interface either under a specific question or in the left hand column of the screen (see screen shot below). It provides a brief explanation or some further detail concerning the nature of the information that should be provided and may include links to external resources or Guidance Topics.
2. **Guidance Topics:** If appropriate, some sections/subsections may include link/s to extended sources of generic information pertaining to ethical issues, that can assist in the completion of specific questions (e.g., *Research Integrity in the Open Scholarship Era)*. These links can be accessed on screen via the help text. Within these MS Word documents, there may be further links to important information, that is not visible directly. The links to the guidance documents are located close to the sections of the form to which they apply (Figure 1).
3. **Specific Research Ethics Committee Guidance**: The aim of this document is to provide generic guidance that is applicable to all users. It may be the case that the REC to which an application is being made, has provided specific guidance that pertains to the faculty/school/discipline considerations. If this is the case, the relevant information will be available via the local REC web page (Under development Michaelmas 2022).

Figure 1: Screen shot of screen and help text

Main Project Details

Title of Project *

test feedback

Data Collection Start Date * **Data Collection End Date** * **Project End Date** *

Does the project involve *

Humans (or their data)

Is the research wholly an analysis of legal judgments/cases/statutes/legal provisions, which has been made public by ajudical process?

- Yes
- No

Only applies to applicants from the School of Law

Are Trinity Researchers only involved in the writing phase and/or the analysis of anonymised data for this project that has approval from an external ethics committee *

- Yes
- No

Could the research have detrimental legal, economic or social consequences for either the participant or their establishments *

- Yes
- No

Intentions of the study: Does the project *

- Involve Deception
- Intend to uncover additional illegal activity
- Explore a topic that is potentially intrusive or is research that is harmful or may endanger the human participants
- Have a military role
- Have a dual purpose that could be mis-directed to do harm
- None of the above

State research aim(s) and objective(s), research question or hypothesis *

Word limit :100 words

Lay Summary: including background/ rationale/ justification, research approach, study design (exclude detail of measurement instruments and intervention and analysis (if applicable) (Word limit: 250 words) *

Main Project Detailss

This section is required for all projects. Read the Guidance Document closely while completing this section

With regard to the question does the project involve 1) humans or their data or 2) animals, if you unable to answer yes to either of these categories, your project may not require ethics approval. If you are a student discuss this with your supervisor. Note if this question is not answered it will be picked up by the system and submission of the application will not be facilitated.

Guidance: Routing
Guidance: Start dates
Guidance: Writing Phase
Guidance: Deception research
Guidance: Intrusive, harmful or can endanger humans
Guidance: Dual purpose
Guidance: Aims and objective (s) and summary
Guidance: Invasive and non-invasive descriptions.
Guidance: Research in a foreign country.
Guidance: Funding

https:https://www.tcd.ie/estatesandfacilities/shared-admin-and-support/insurance/ccccccc
https:https://www.dfa.ie/travel/travel-advice/

1. Abbreviations and terminology

2.1 Abbreviations

AREC: Animal Research Ethics Committee

DPIA: Data Protection Impact Assessment

DPO: Data Protection Office

DPRA: Data Protection Risk Assessment

GDPR: General Data Protection Regulation

HPRA: Health Products Regulatory Authority

PI: Principal Investigator

PIL: Participant Information Leaflet

REAMS: Research Ethics Administration Management System

REC: Research Ethics Committee

RSS: Research Support System

RPAMS: Research Proposal and Application Management System

TR&I: Trinity Research & Innovation

2.2 Terminology

Given a diversity of research domains, it is inevitable that several different terms can be used to convey approximately the same meaning. Within the REAMS systems, and in this guidance document, only one term is used to convey a particular meaning. The specific terms were selected based on adequacy, and the manner of their current use across Trinity in the context of ethics applications. In this section, the main terms are defined.

- **Adverse Event:** is any event that causes harm or distress in the context of research involving animal or human participants. The risk section in the application form requires that applicants to identify the potential for adverse events and indicate the steps to be taken to mitigate against any such events. It is requirement when ethical approval has been granted that adverse events are reported to the approving ethics committee. Details of adverse event reporting policy currently under development.
- **Amendment:** Changes made to an ethics application after receiving approval.
- **Applicant**: The applicant is the **one** named researcher who has primary responsibility for the ethics application. This person will receive official correspondence concerning the application, including the outcome of review. It is expected that this person will respond to any requirements arising from review. In most cases (including

submissions by students), the applicant will also be Principal Investigator (PI) for the project (see below for PI definition). In some large projects, the role of applicant may be delegated to another member of the research team, who is not the PI. In such cases, the PI must tick the appropriate declaration, and approve the application, as part of the submission process (See PI below for more information).

- **Attachment:** An attachment is any additional document required to be submitted with the application. For example, when the answer is yes to the question: *Will consent be taken from the participant?* the system will register that an attachment of the consent form is required. An attachment tab will appear at the top of the page. When the application form is otherwise complete, opening the attachment tab will reveal a list of all the attachments that are required and an interface for their uploading. Submission of the application will only be possible when all the attachments on this list have been uploaded. (See section 3.5 below for further detail on the attachments that may be required).

- **Collaborator:** The term collaborator is the generic term used in the application for all other members of the project's research team. This term is synonymous with investigator, co-investigator, co-applicant and includes Academic/ Clinical/Professional/ Industrial Collaborator and Public or Participant Collaborator

- **Committee Review:** This is the term used in the present document for the traditional means of evaluation by a research ethics committee, see also expedited review and Section 4 below for further detail).

- **Expedited Review**: In line with the Policy for Good Research Practice all research ethics committee have a pathway that permits certain projects to be reviewed in a fast-track manner for example those that have ethics approval from other recognised research ethics committees (see Section 4below for further detail).

- **Principal Investigator:** Principal investigator (PI) is the term used to identify the person responsible for the preparation, conduct and administration of a project and (if applicable) of a corresponding research grant. This person will usually also be the one responsible for the ethics application (i.e., the Applicant). Most students will be both the PI and the Applicant. In such cases, a supervisor declaration section will be generated. For the application to proceed, this must be completed by the primary supervisor. In some large projects, the role of applicant may be delegated to another member of the research team, who is not the PI. In such cases, the PI must sign the appropriate declaration, and approve the application, as part of the submission process (See also Applicant entry above).

- **Project:** Throughout this documentation, the term project applies to the research that is related to an ethics application. In most cases synonymous with study, thesis, proposal.

- **Participant/ potential participants**: This term is used synonymously for subject, data subjects, individuals, animals.

- **Administrative Data**: This is administrative information collected through the course of the project which is not directly related to the aims and objectives of the study. It is not research data (see below Research Data). It may include Personal Data (as defined under the General Data Protection Regulation and are subject to being

processed, retained and destroyed in line with Trinity policies. These data may include schedules, contact details, consent forms You will be asked to identify data of this nature in your application.

- **Research Data:** "Research data are data that are used as primary sources to support technical or scientific enquiry, research, scholarship, or artistic activity, and that are used as evidence in the research process and/or are commonly accepted in the research community as necessary to validate research findings and results. All other digital and non-digital content have the potential of becoming research data. Research data may be experimental data, observational data, operational data, third party data, public sector data, monitoring data, processed data, or repurposed data" (Policy for Good Research Practice) . It also includes the codes linking the original data to the pseudonymised data.
- **Revision:** This is a version of the application that has been amended to satisfy changes requested by the REC, and which must be provided before ethics approval can be granted.
- **Supervisor:** All students conducting research will have at least one supervisor. The main or singular supervisor is called the primary supervisor. In line with Trinity policies, the primary supervisor for Post Graduate students is generally a member of Trinity academic staff. All supervisors, both Trinity and non-Trinity, must be named as collaborators within the ethics application. For all student applications, the primary supervisor will be required to complete a declaration before submission can proceed. Applicants who have a primary supervisor that is external to Trinity, must contact the relevant research ethics committee they are applying to, to facilitate this.

2. Preparation for ethics approval submission

Preparation of an application for ethics approval should commence well in advance of the anticipated date of submission. This is necessary to ensure sufficient familiarity with ethics and data protection procedures, that all relevant and applicable training has been completed by members of the team, and that all documents required as part of the submission are available. Please leave adequate time for the completion of the form especially if you are a novice researcher and remember it may have to be approved by the PI and/or primary supervisor before submission is permitted. Think weeks rather than hours or days for the preparation process as a whole. As you complete the application, the characteristics of your project will determine the questions/sections that are appropriate to your project. You will only be presented with relevant questions/sections.

3.1 Education and course requirements for research ethics and data protection

Please consult the Policy on Good Research Practice for detailed discussion of good research practice and the role of research ethics and approval review.

3.1.1 All Trinity applicants, their supervisors (if the applicant is a student), and principal investigators (if applicable), in projects involving humans must complete and attach an up-to-date (annual update) Data Protection Training Module certification before submission will be permitted.

3.1.2 If a project is subject to the provisions of GDPR, all Trinity collaborators must complete and attach an up-to-date mandatory Data Protection Training Module certification, before submission will be permitted.

3.1.3 With the exception of PhD students who are Trinity members of staff, PhD students must complete and upload certification of completion of Research Integrity in the Open Scholarship Era Training before submission will be permitted.

3.1.4 Applicants will also find useful information about the classifications, storage and management of their research data at the following sites

- Policy on Good Research Practice
- Data classification - IT Services - Trinity College Dublin (tcd.ie)
- Research data storage: https://www.tcd.ie/itservices/working-remotely/research-data/

3.2 Which ethics committee?

The school and departmental affiliation of the applicant or PI, and the characteristics of the project, will together determine the risk level and type of review that applies to each ethics application, and therefore the REC to which it will be routed for review (Section 4). Review of this section and Section 4 will enable applicants to determine the REC a project will be routed to. Applicants should bear in mind that each REC is likely to have fixed dates of submission. These dates can usually be found on the REC local webpage. Note that, within the system, routing is automatic. It is governed by the characteristics of the project as cited above. If you make any erroneous assumptions concerning the characteristics of your project, it may not be routed to the anticipated REC.

When your start a new application the risk for the project will be ranked as Risk 2 as a default and this will appear beside the project name on the top of each page. Once the project details page has been completed and saved, this will change to reflect the true risk of your project and therefore the level of ethics committee it will be routed to, and whether it will undergo expedited or committee review. In the figure below the applicant has completed the project details page and has been assigned a Risk level of 2E. Therefore, the applicant will be routed to their local Level 2 ethics committee and the application will take the expedited route. Applicants should consult the relevant ethics committee local webpage to

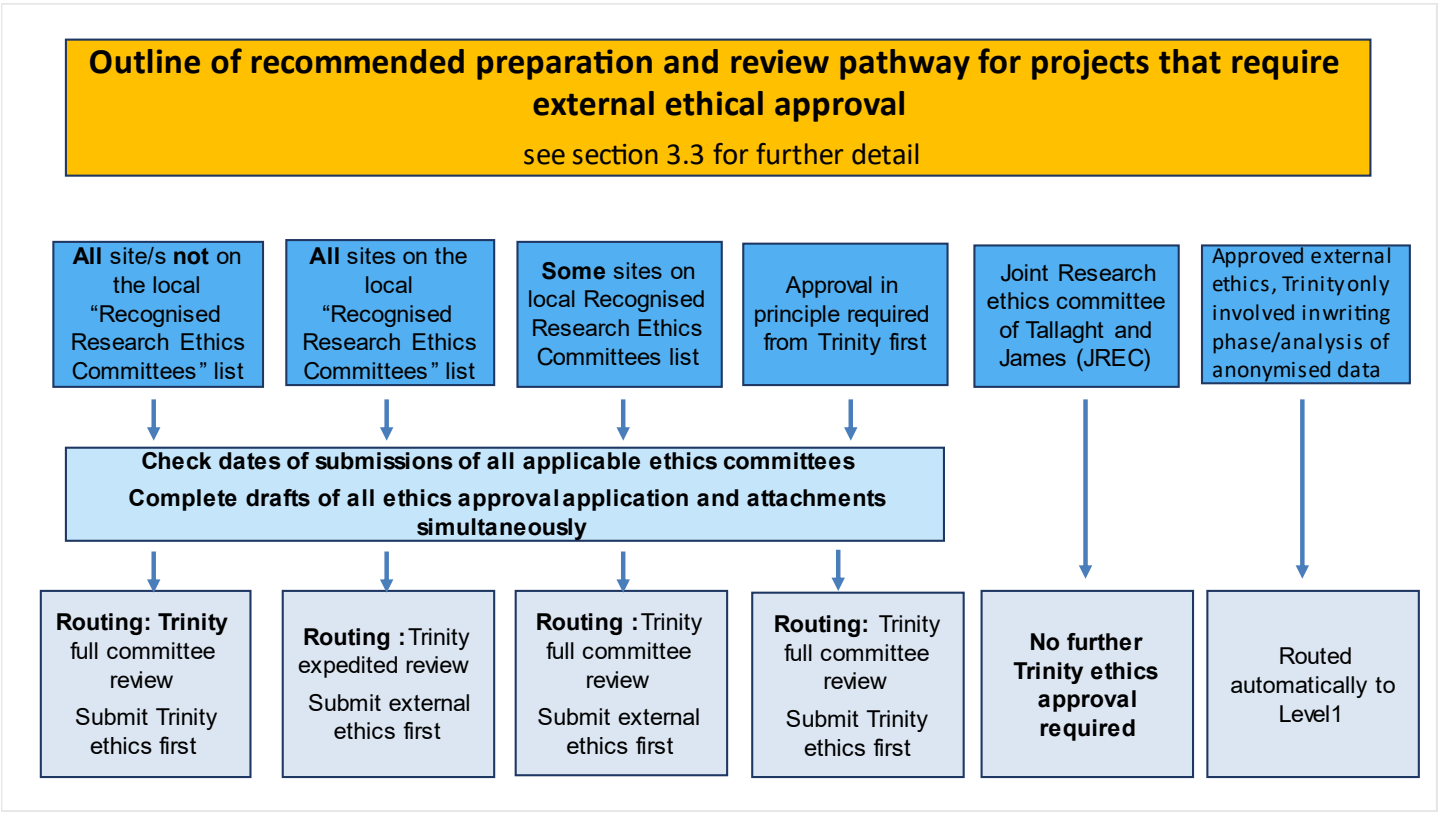
ascertain what specific deadline dates of submission apply for this type of submission. Further information concerning designated levels of risk and expedited review is provided in Section 4 below.

3.3 What if you have or require ethics approval from another ethics committee?

All research undertaken by Trinity staff or students, which involves animals, humans, or human data (excluding archival data) requires some level of ethical review from Trinity, (see JREC 3.3.6 below) irrespective of whether the data are collected at a different institute/s, and regardless of whether ethics approval has been granted by another institution.

In respect of research projects for which there is existing ethics approval/ animal licence from an appropriate external body or a Recognised Research Ethics Committee, ethical approval must also be obtained from Trinity. In some cases, these applications will be eligible for expedited pathway and review (see below). Usually, it is required that the external documentation is complete and has been approved or has been "approved in principle" (the only pending item being the provision of approval by Trinity) (see below and Figure 1).

Figure 1: Recommended pathways for projects requiring external ethical approval



3.3.1 It is essential to prepare the Trinity ethics application form in conjunction with the external form/s to ensure that all information required by Trinity is included on the external ethics application and that the level of detail provided across both (all) applications is compatible. This will help prevent extensive revisions being required by the different approving parties.

3.3.2 With the exception of projects involving animals, it is recommended that ethical approval is obtained first from the relevant external Recognised Research Ethics Committees (see below 3.3.3). Once this is accomplished, expedited review by Trinity ethics may be requested.

3.3.3 The research ethics application forms used by external ethics committees are generally similar to those used by Trinity. There may however be important differences that reflect the distinct character of other institutions. Ethics committees in Trinity have extensive experience with the forms used by external ethics committees, and on this basis have generated a list of Recognised Research Ethics Committees. The forms used by the institutions listed generally meet Trinity requirements. Only projects for which all their research sites are drawn from the local list of Recognised Research Ethics Committees can be expedited.

3.3.4 Some external ethics committees will first require approval in principle from Trinity before they process their local ethics application. In these cases, expedited review by Trinity is not available. The system will direct these applications for full committee review.

3.3.5 Only projects for which **all** the external ethics approvals have been obtained (or in some limited cases "approved in principle") can be expedited. If this is not the case the application will require committee review. It is expected that an applicant should make every effort to have all external ethics approval in place when submitting. If that is not possible, applicants may apply for approval in respect of the sites for which there is completed documentation (or approved in principle), and subsequently seek to obtain approval for additional sites through the amendment process. Applicants are cautioned that amendments that deviate from minor changes may be require a full application.

3.3.6 Health Sciences: Projects that have ethics approval from the Joint Research Ethics Committee (JREC) (St James's and Tallaght University hospitals) – by virtue of their Trinity affiliation, do not require additional ethical approval from Trinity. If, however, any such projects require a hospital Data Protection Impact Assessment (DPIA), this must be submitted to the Trinity Data Protection Officer (DPO) for review. If the project includes other sites (in addition to those covered by the Joint Research Ethics Committee (JREC) (St James's and Tallaght University hospitals) ethical approval by a Trinity REC is then required.

3.3.7 In the cases in which ethical approval has been granted by an external ethics committee, site, the submission to Trinity research ethics committee must include: The previously approved ethics application form including all supplementary appendices, attachments, and (as applicable) any agreed data protection documentation (DPRA / DPIA), together with the letter of approval.

Please consult the relevant Trinity REC during early planning/ before submission if the approving external ethics committee is not listed as a Recognised Research Ethics Committee, or if the application materials are in a language other than English, to ascertain if a full application is required.

3.4 Which approvals are required before submission is possible?

In the case of all student applications, primary supervisors must approve the application before it can be submitted. It is critical therefore that sufficient time is allocated for the primary supervisor to review the application, and for any recommended revisions to be implemented (i.e., in advance of a REC submission deadline).

If the applicant is not the PI, the project PI must approve the application to make possible its submission.

As outlined in 3.3, if ethics approval / licence (including animal studies licence) is required for another site/ institution, this approval/documentation and (if applicable) any related data protection documentation (i.e., DPRA, DPIA), must be completed, approved and uploaded prior to submission.

3.5 Which attachments are required before submission is possible?

As the form is being completed, a list of required attachments will be generated. For a submission to be made, all required attachments must first be completed and uploaded. Starting an application early will allow identification, development, and completion of all relevant documents. The necessary steps could include, for example, obtaining permission to access a site or database, completing the Garda vetting application, completing GDPR training. See below for a list of potential attachments.

If a Participant Information Leaflet is required, a template will be generated with information exported from the application and some guidance. This can be adapted to ensure that it is suitable for the study in question.

The REAMS application contains all necessary questions relating to data protection. Depending on the nature of any personal or special category data associated the project, the system will assess the documentation required and (if applicable) generate a DPRA/DPIA for completion. Once completed, this documentation will be routed to the DPO for review in parallel with that undertaken by the Research Ethics Committee (REC).

3.5.1 List of attachments that may be required depending on the project's characteristics (alphabetical order).

Animal participant projects

Animal Licence(a)

- External animal licence for project

If your application is a first submission to AREC

- Short AREC application form
- HPRA project application form
- HPRA NTPS template (excel document)
- Project protocol (AREC)
- Score sheets (AREC)

If your AREC project is an amendment to an approved application, please append the following attachments

Cover letter (AREC)

- Final approved version of the AREC form
- HPRA project amendment application form
- Final approved version of project protocol
- Final approved version of the score sheets
- Final approved version of the original HPRA application
- (Any additional documentation pertaining to the current amendment

Human participant projects

- Approval from another REC (finalised approved application form, approval letter and related appendices)
- Documentation indicating permission/authority to access site or data source
- Consent form
- Explicit consent form or informed consent form
- Data collection instruments (all)
- Data extraction list
- interview schedule / observation schedule/ other
- Questionnaire/s

Other

- Data protection Training certificate (applicant, primary supervisors, PI in all instances and all other Trinity members if the project involves the processing of personal data)
- Data Protection Impact Assessment (DPIA) (Final) from external site/s including all amendments
- Declaration and guidelines for interviewing or testing with adults or children (School of Psychology only)
- External ethics approved application form
- Garda Vetting Clearance
- Joint data controller agreement
- Letter of agreement / permission to access from institutions/organisations agreeing to host the research project, assist with participant recruitment, access to data etc.
- Letter of agreement / permission to access staff or students of Trinity (e.g., school, Faculty Dean, Director of Research, Director of UG or PG programmes) agreeing to host the project, assist with participant recruitment etc. addressed
- Licence to access source
- Methods, measurement used
- Non-disclosure agreements or other such agreements for third parties such as companies involved in doing transcriptions
- Participant information leaflet
    - Participant assent form
    - Permission to access site
    - Processor agreement
    - Recruitment documentation
    - Research integrity module certification
    - Research Consent declaration
    - Trinity staff access permissions
    - Trinity students access permissions

3.6 Other general information

It is recognised that recruitment from the general population may unwittingly include some participants that are at risk of vulnerability. While this may be acceptable in many cases (except if the participants are children), for all project types, the appropriate safeguards must be in place.

There are specific protocols to be observed by Trinity staff and student researchers who are seeking to recruit staff and students of Trinity as participants

There are additional access and ethics processes that must be followed if the researcher is external to Trinity (Policy on Access to Trinity College Staff and Students for Research Purposes by External Organisations).

Guidance: Mixed Methods

Projects that will involve the collection of data using different methods in distinct phases require separate ethics approval for each phase. An exception may apply only for projects that involve the same access/ recruitment methods, and the same population in all phases, and in which the phases are not dependant on one another (i.e., phase 1 develops a questionnaire to be used in phase 2).

4. Characteristics that define the assessed risk of projects and the resultant routing pathways

It is important to understand this section, as the system will automatically route the application to the appropriate REC prior to submission, and each REC may have specific submission deadlines.

4.1 Overview of assessed risk of project

Within the REAMS system, the routing of human research projects to a specific REC is automatic. Routing is based on three main elements

Whether the project involves animal or human research: In the project details section, it will be determined whether the project includes animal or human participants. This will dictate not only the tabs sections that will then have to be completed by the applicant, but also the routing of the application.

School and Faculty of the applicant: Depending on the assessed risk of the project (see 4.3 below) projects will be routed to the relevant local Level 2 or 3 committee (see section 8). In addition, some centres have their own REC and members of these centres should use these centres as their affiliation address if they wish to be routed to these committees.

Assessed risk level of application.

4.2 Risk level of application.

4.2.1 Projects involving Humans or their data

From an ethics perspective, the assessed risk is determined by certain characteristics of the project. Based on this determination, each project will be classified as either very low-risk, low-risk, or moderate to high-risk.. This classification in turn dictates the review level (1, 2 or 3) that is appropriate for the application. and for projects involving human participants or data in Table 1b. They may be summarised as follows:

Level 1 (Human):

- Very low-risk research has no apparent risk to the participant
- Projects must have all the following characteristics:
    - conducted in non-vulnerable participants (never children)
    - explores a non-intrusive topics
    - conducted using low-risk methods
    - the participants cannot be identified either directly or indirectly in either the research data or other administration data i.e., contact details.

Level 2 (Human):

- Low-risk research carries no greater risks or discomfort to the participant than usually encountered during normal daily life.
- Projects must have all the following characteristics: conducted in non-vulnerable participants (never children), explores a non-intrusive topic and does not employ any of the methods or project types listed under Level 3 (see Table 1a).

Level 3 (Human):

- Moderate to high-risk research, is research where the risk or discomfort is greater than that usually encountered during normal daily life.
- Projects that are
- conducted in vulnerable participants (including children)
- explore intrusive topics
- employ any moderate to high risk methods or project types (see Table 1a).

Table 1a: Summary characteristics that determine the risk levels of projects with human data or participants

REC Level 1: **Very low risk**	**REC Level 2:** **Low risk**	**REC Level 3:** **Moderate & high risk**
No identifiable data	Identifiable and non-identifiable data	Identifiable and non-identifiable data
Non-intrusive topics	Non-intrusive topics	Intrusive topics
Low risk of vulnerability	Low risk of vulnerability	Moderate or high risk of vulnerability, particularly where participants recruited are: • Children (under 18) • Prisoners • Asylum Seekers • Participants who require support to give consent • Participants with a dependant relationship with the researcher
None of level 3 criteria	None of level 3 criteria	Other level 3 criteria
Low risk methods • Quality assurance studies • Anonymous Surveys • Unrecorded and anonymous observation of individuals in public areas	Most methods except those cited as specifically Level 3 Non-invasive biological samples	**All methods, but specifically:** • Projects involving a degree of deception • Research involving collection of non-invasive biological samples or tissues hair, nails, saliva, semen, urine, buccal epithelial cells in **patient** populations

• Audits of standard practices or tests
• Data from a secondary source
  ▪ Publicly available information
  ▪ Non-publicly available data source with permission
Special low Risk Methods: Projects routed to Level 1 based on the following characteristic only:
• Trinity Researchers only involved in the writing phase and/or the analysis of anonymised data of a project that has approval from an external ethics committee.
• Projects that are wholly an analysis of legal judgments/ cases/statutes/legal provisions, which has been made public by a judicial process.
		• Research involving invasive procedures of any kind or the collection of **invasive** (see Guidance) biological samples or tissues or blood samples (except pin prick) from human (healthy or patient) volunteers.
		• Research involving the collection of biological samples by any method or of any size yielding information including genetic analysis that could impact upon treatment (e.g., Human DNA sequencing).
		• Research involving interventions that are not usual practice that could have an impact on participants i.e., testing a new teaching methodology, a new psychological or care intervention.
		• Research that intends to identify illegal activity.
		All projects that have a high risk, specifically
		• Research where information obtained may have legal, economic or social consequences for research. participants or their establishments.
		• Health Research Projects that require consent declaration form as defined by the Health Research Regulations 2018, & amendment 2021.
		• Projects where each participant is paid (over and above token gestures and expenses) (See Guidance Gift Voucher Policy.
		• Research that has a military role.
		• Research that may have a dual purpose that could be misdirected to do harm.

4.2.2 Projects involving Animals

From an ethics perspective, the assessed risk is determined by certain characteristics of the project. On the basis of this determination, each project will be classified as either very low-risk, low-risk, or moderate to high-risk. The characteristics that determine the assessed risk for animal studies are detailed below in Table 1b.

Table 1b: Summary characteristics and project routing for animal research

Guidance AREC:

Research in the laboratory setting that involves vertebrate animals (including foetal forms of mammals beyond two thirds of their development in utero) and cephalopods. Projects that fall under this category will be routed to the animal research ethics committee (AREC) (committee review).

1. **Very low risk wildlife and ecology projects**: these projects will be routed to Level 1 and if student projects will be reviewed by the supervisor
    a. Sampling sustainable numbers from populations of invertebrate subjects (other than cephalopods), irrespective of subsequent processes.
    b. Observations of vertebrate subjects left undisturbed in their natural environment,
    c. Non-destructive measurement or observation of wild / managed environments
    d. Translocations of small numbers (compared to local population sizes) of individuals of a native species between sites all within the local area

2. **Category 1: Low risk wildlife and ecology projects.** These projects will be routed to the School of Natural Sciences REC as they are low risk (Level 2), they will take the expedited review route.
    a. Translocations of large numbers of individuals of a native species or from further than they can travel naturally, or of non-native species.
    b. Capture and removal of wild vertebrates, under licence from the relevant specialist body, or those deemed vermin.
    c. Brief (less than a 2 hours) capture of small numbers (as a proportion of the local population) of wild vertebrates and return to their original site of capture.

3. **Category 2: Low risk wildlife and ecology projects.** These projects will be routed to the School of Natural Sciences REC (Level 2) as they are slightly higher risk than Category 1 they will take the committee review route.
    a. Capture and removal of wild vertebrates without licence from the relevant specialist body
    b. Translocations of large numbers of individuals of a native species or from further than they can travel naturally, or of non-native species

4. **Moderate risk wildlife and ecology projects.** Because of the higher risk of these projects, they will be routed to the Level 3 committee
    a. Studies involving vertebrate wildlife, suffering pain, suffering or lasting harm beyond that inflicted by a trained vet giving an injection
    b. Permanent damage to wild populations or environments
    c. Additions of alien or invasive species

5.

4.3 Personal Data (Human studies)

If your project involves the processing of Personal Data (as defined below), you will be routed to Level 2 or 3.

Only very low risk research projects that use irrevocably anonymised data and administration data that has no personal data can be routed to Level 1.

For the purposes of this section Personal Data means information about a particular living individual, which can directly or indirectly identify them. Personal data includes information which has been pseudonymised i.e. (identifying characteristics replaced with a pseudonym or a value which does not allow the individual to be directly identified, and a key to link the two is kept separately to the source data). For further Information see: *Guidance: Personal data*.

4.4 Risk of vulnerability in humans

Participants who are at risk of vulnerability are not always vulnerable; their vulnerability may change with the situation and environment; their vulnerability may change over time. For example, the nature/ topic of the research itself may influence whether a project with participants at risk of vulnerability would be routed to a Level 3 REC (See Guidance and Policy for Good Research Practice). Trinity research policy gives special consideration to protecting the wellbeing of individuals at risk of vulnerability. Therefore, projects from the following groups are always routed to Level 3.

For the purposes of this Section, vulnerable means but is not limited to any participants from the following groups:

- Children: For the purposes of research children are anyone under the age of 18. All projects involving child participants, or their data, are routed to Level 3 REC.
- Prisoners.
- Asylum seekers: these are migrants that are driven from their home.
- Persons who require support to give consent:
    - these may include adults with mental health illnesses, one or more learning disabilities, literacy difficulties, cognitive impairments or communication disabilities. Not all the people in these groups will require support to provide consent and where this is the case, depending on the other characteristics of the project, these projects could be routed to Level 2 (Low risk) (see below).
- Participants who have an unequal power relationship with the researcher e.g., student/ lecturer, employee/ manager, carer clinician / person they care for that cannot be mitigated for.
- Participants who have just been diagnosed with a life –limiting/threatening condition/dies or who are terminally ill.

As cited above, if the participants could be considered vulnerable but have capacity to provide informed consent without support, these projects could be routed to Level 2 (Low risk), if the other characteristics are appropriate. Participants who may be at risk of vulnerability can be supported indirectly by ensuring that the Participant Information Leaflet is accessible and suitable for their capabilities, that they have capacity sufficient to understand the information being provided and can volunteer independently to be part of the project. If participants who at risk of vulnerability require further support to partake in the project, then the project is deemed to be of a higher risk and will be routed to Level 3.

4.5 Intrusive topics (Human studies)

While all research involving human participants is intrusive to some degree, intrusive topics are those likely to cause risk or discomfort greater than that usually encountered during daily life. It is considered that these put the participant at higher risk. Projects that collect data concerning intrusive topics will be routed to a Level 3 REC.

For the purpose of this section Intrusive topics include but are not limited to any of the following topics: abortion, abuse, bankruptcy, bullying, child abuse, gun control, self-harm, trauma or whistleblowing.

4.6 Low risk methods (Human studies)

The methods used in different projects vary significantly and consequentially they differ in their risk. To be classified as very low risk research and routed to a Level 1 pathway, a **project must use only methods** from the following list

- Anonymous data collection e.g., surveys
- Audits of standard practices or tests (see *Guidance: Audits of standard practice and /or quality assurance/ quality improvement studies)*
- Data extraction from publicly or non- publicly available (with permission) data (see *Guidance: Publicly available data)*
- Quality assurance studies (see *Guidance: Audits of standard practice and /or quality assurance/ quality improvement studies)*
- Unrecorded (no audio, visual or electronic recordings etc) and anonymous observation of individuals in public areas
- Data from a secondary source (see *Guidance: Secondary Analysis*)
    - Publicly available information
    - Non-publicly available data source accessed with permission
- **Special low Risk Methods:** Some projects are routed to Level 1 based on the following characteristic only:
    - Trinity Researchers only involved in the writing phase and/or the analysis of anonymised data of a project that has approval from an external ethics committee.
    - Projects that are wholly an analysis of legal judgments/ cases/statutes/legal provisions, which has been made public by a judicial process.

4.7 Projects and methods that are automatically High risk and routed to Level 3 (Human studies)

As indicated in Table 1a, projects are always routed to Level 3 if they explore intrusive topics or recruit participants that have a particular risk of vulnerability. In addition, methods or projects that are considered to be moderate or high risk are also routed to Level 3 ethics committees. The relevant characteristics are listed in Table 1a above.

5. The review process and outcomes

5.1 The objective of reviewing

Researchers are entitled to an ethical review system in which decisions flow from clear policies, are applied evenly, are discipline appropriate, and are without bias or prejudice. It is reasonable to expect that reviews will be comprehensive, fair and carried out in a timely manner by competent, knowledgeable, appropriate diligent reviewers.

The main purpose of ethical review is the protection of the animal and human participants. The principles applied in respect of human research are based on the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. These principles include respect for persons and their autonomy, beneficence, non-maleficence and justice (achieving a favourable risk benefit ratio) across all aspects of a research project. It is recognised that the conduct of research can also present risks for researchers. The protection of researchers and research sites are further purposes of ethical review. These should also be given specific consideration when preparing an application. A broadly similar set of principles are applied in animal research (Policy for Good Research Practice).

Main areas of review

- That the benefits of the project are likely to outweigh the risks to the participants.
- Participants and their data are protected while permitting human participant autonomy.
- Potential ethical issues, including risk to researchers, are identified and brought to the attention of researcher, with a view to ensuring that the research is ethically sound.
- Consideration is given to the suitability of the proposed research methodology, in so much as this bears upon the ethical integrity of the project.
- Ensuring that research conducted under the auspices of Trinity complies with Trinity standards, regulations, and legal requirements and obligations.
    - In human studies this applies particularly in relation to privacy legislation. With respect to applications that do not also require a DPIA, it is expected that a Trinity REC review will ensure compliance with all relevant data protection requirements and regulations.

Reviewers will expect that ethics applications are written with sufficient clarity, and that the project is described in a level of detail sufficient to ascertain if it is ethically sound. It is not the purpose of the ethical review to:

- Serve in lieu of supervision
- Assist in the development of a project
- Correct minor matters of methodology or design
- Proof-read the documentation and correct errors in spelling, grammar and syntax
- Correct or make editorial changes to already validated data collection instruments

This noted, major inadequacies in any of these areas may result in a decision that the application is rejected, or that major revision are required. In some cases, particularly major revisions and rejects, specific feedback will not be provided. If, for example, the revisions are too extensive or have too many implications for other sections in the application or the methodological rigour of the proposed project is so poor that it is not likely to succeed in achieving the objectives of the study, or if it may increase the risk of harm to participants, the reviewers will not necessarily indicate the means by which such deficiencies should be addressed.

5.2 Review outcomes

There are four potential review outcomes of ethical review: approval, minor revision, major revision or reject. The outcome that an ethical application receives will dictate when revisions can be submitted and therefore the potential length of time before approval is finally achieved.

5.2.1 Approval

After review by a supervisor, expedited or committee pathways an 'Approved' outcome indicates that all ethical considerations have been addressed and appropriate data protection requirements are deemed to be in place. Only once approval has been granted, can data collection commence (in accordance with the dates indicated in the application).

5.2.2 Minor Revision

Minor revisions reflect an adjudication that the application provides adequate detail, accuracy, and consistency across sections, and that the supporting documentation is largely appropriate and complete. For minor revisions, the subsequent resubmission of an amended/corrected application will be dealt with in a shorter time frame that that required to assess the initial application. The resubmission of an application following decision of Minor revision outcome will not require further declaration by a supervisor or PI. Within term time, RECs will seek to ensure that the time required for period for review of a resubmission of an application following a decision of Minor revision is as short as possible.

The following are typical of applications deemed to require **Minor revision**.

- A requirement for minor changes to one section of the application that do not result in changes to other parts of the documents, appendices or attachments.
- Minor omissions of important information.
- Content errors which are few in number.
- Approval in principle: In certain cases, Trinity approval at least in principle is required by an external agency before their documentation is finalised/ approved. Trinity approval cannot be finalised until all such

external documentation is complete and uploaded. An examples of such circumstances is when a project requires a consent declaration, or access permission. In these cases, when all other outstanding revisions and issues are addressed, the project will be given a Minor Revisions outcome, along with an explicit indication that final approval is contingent upon confirmation from the external agency.

5.2.3 Major Revision

A decision of Major revision is made if an application is insufficiently detailed, contains inaccuracies or inconsistencies across multiple sections and/or documents. With respect to Major revisions, the subsequent review of a revised application may not occur prior to the next submission date for the applicable REC. A project with a Major revision outcome will also require reapproval (if applicable) by the supervisor and/or PI, prior to resubmission. In many such cases, the degree of required revisions will include major redrafting, that may extend to several sections of the application and/or documentation.

The following are typical of applications deemed to require Major revisions:

- Several ethical issues were identified.
- The revisions will involve multiple changes or the provision of new information in the application or supporting documents.
- Inconsistencies detected across the application and the supporting documentation.

5.2.4 Reject

This is expected to be a rare outcome. It would reflect a project so poorly developed, and with ethical and/or data protection issues so substantial that an entire reconstruction of the project and application will be required. The following are typical of applications that may receive a reject outcome. As noted, the feedback provided concerning such applications is likely to be minimal.

- Research that is ethically unsound and is unlikely to receive ethics approval even following major changes. This may include research deemed to have a poor risk/ benefit ratio.
- Poorly written applications, that lack sufficient detail, and include substantive errors, or omissions.
- Research that has already commenced.
- Retrospective research. This may include for example, instances in which an innovation has been introduced and evaluated, and the researcher now wishes to apply for ethical approval so that they can publish the results. Depending on the aim of the project/analysis some retrospective database analysis may be undertaken without further ethical approval (see *Guidance secondary analysis*)

5.3 Review Cycle

Once an application has been reviewed, the applicant will receive notification of the outcome, and the outcome will be visible to them, their primary supervisor (if applicable), and the project PI (if applicable) within the system, and if applicable will include feedback indicating any required revisions. The status of the application will be reset to once again permit editing by the applicant.

5.3.1 Amendments

Amendments is the term used when an applicant requests a change to their application after approval is granted. Amendments do not include subsequent rounds of data collection or another phase of a study using a different methodology. For these, a new ethics application is required. After approval has been granted by a Research Ethics Committee, an applicant may need to seek approval for changes which are necessary to maintain or enhance the integrity of the research project. Amendments are *minor* changes such as the inclusion of an additional member of the research team, the addition of a new data collection site, limited changes to the protocol that will not have a major impact on the content of the participant information leaflet, DPIA etc. Minor changes to the wording of an interview schedule, for example, do require that an amendment be submitted, unless the content explored is substantially different. Student applicants are advised to discuss and consult with their supervisors when changes of any kind are being contemplated, in order to ascertain if they are likely to meet the criteria for an amendment. More details on how to submit an amendment are included in section 7.

5.3.2 Appeal

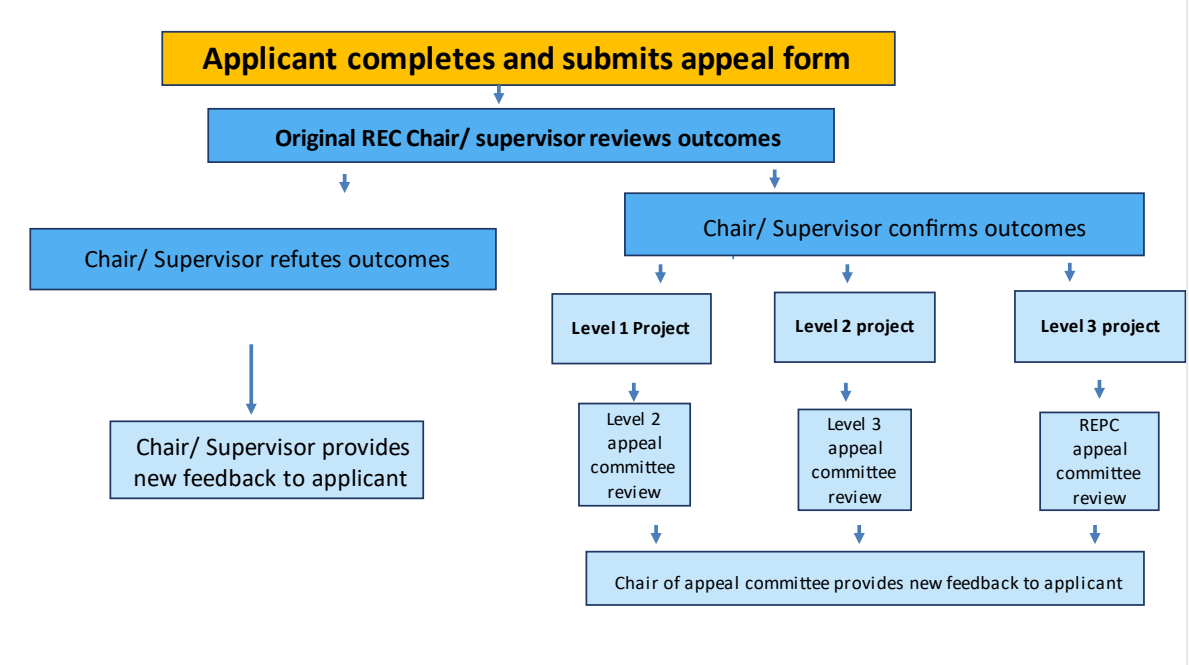
In the unlikely event that the applicant disputes the basis of a **major corrections or reject** decision, there is an appeal pathway. The appeal committee for Level 1 appeal is the Level 2 REC within the same Faculty with expertise most relevant to the content of the application. Likewise, the appeal committee for Level 2 appeals is the Level 3 REC within the same Faculty with expertise most relevant to the content of the application. The Research Policy Ethics Committee (REPC) acts as the appeal committee for Level 3 RECs and animal application appeals (Policy for Good Research Practice).(see Figure 2 below)

1. The applicant completes appeal form (to be developed and linked here) and submits it to the email of the REC to which the application was made. In the case of some Level 1 applications submitted by students, the appeal should be directed to the supervisor in the first instance.
2. On the appeal form the applicant should state clearly the grounds for appeal.
3. If the applicant is a student (for appeals originally submitted to Level 2 or 3) or someone other than the PI, the appeal form must be countersigned by the relevant parties (i.e., supervisor or PI).
4. The chair of the REC to which the application was made (or supervisor in the case of Level 1 appeals), will scrutinise the application, the outcome, feedback and the appeal documentation and decide

whether the outcome they have given is justified and that therefore the applicant has to make a formal appeal. This is a common practice in ethics appeal processes to identify if the decision or elements of the feedback are erroneous and can be corrected without escalation. If the Chair of the REC (or supervisor in the case of Level 1 appeals) deems that the decision or elements of the feedback were erroneous, this finding and a modified decision/outcome/feedback will be communicated to the applicant. In such instances, if this satisfies the applicant an Appeal Committee will not be formed.

5. If the Chair of the REC (or supervisor in the case of Level 1 appeals), affirms the original decision, the full application, original review documentation, and the appeal documentation will be made available to the appropriate REC appeal committee for review.
6. The Chair of the REC designated to deal with the appeal will set up an appeal committee, which they will chair. In addition to the chair, the appeal committee will include at least one reviewer with specialist knowledge relating to the subject matter of the application, and three additional reviewers (i.e., a total of five members). If necessary, members of the appeals committee may be co-opted from other RECs within the Faculty. Members of the appeal committee cannot however be members of the original reviewing REC. All members of the appeals committee are to review the documentation.
7. With the exception of the original review documentation, the appeal committee will work independently of the original committee to make a decision in relation to the application and provide feedback outside the REAMS system.
8. The outcome of the appeal will be communicated to the applicant, Chair of original REC, and if applicable the PI and supervisor.
9. In the event that the applicant does not accept the decision of the appeals committee, further appeal mechanisms are available (detail under development).

Figure 2: Flow Diagram of appeal process

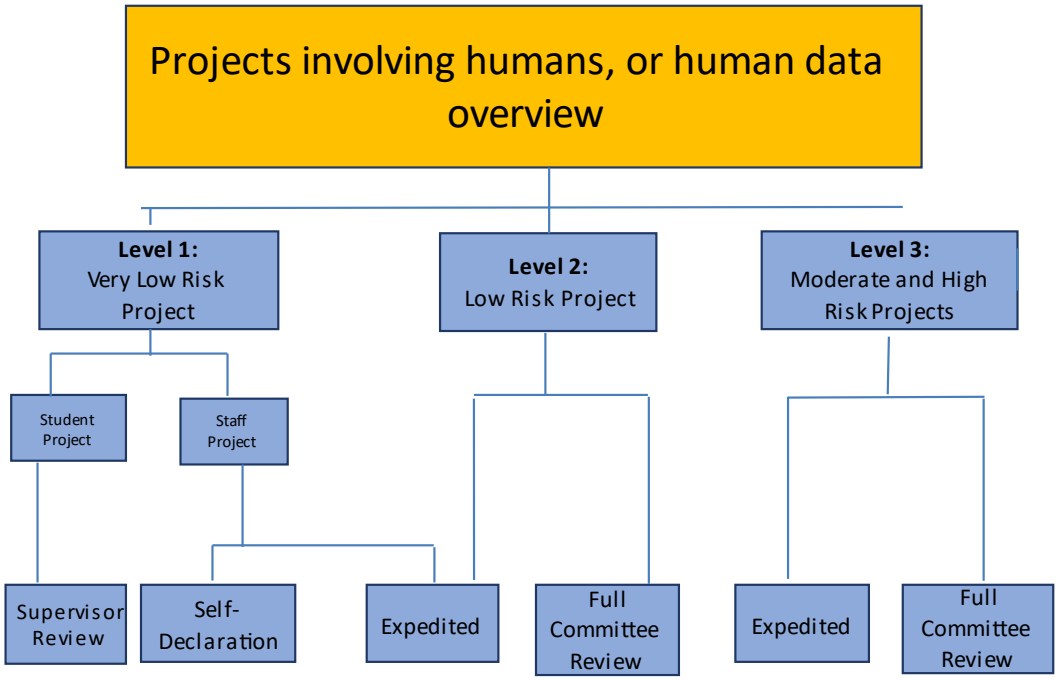


6. The different types of review, supervisor, expedited and committee

6.1 Introduction

As described in Section 4 the parameters of Animal or Human research, School / centre of the applicant and assessed risk will dictate the appropriate REC for review of the application (see Section 8). The present section provides further detail concerning the review pathway. Potential Level 1 review pathways include supervisor approval, self-declaration, or expedited review. With respect to Levels 2 and 3, the review pathway may involve either committee review or expedited review. The exception is applications to AREC, for which only committee review applies.

Figure 1: Draft 1 overview of main routing pathways



6.2 Level 1 review

In the case of Level 1, an ethics application can be submitted on any date during term time and reviewed in line with local procedures for Level 1 and expedited research (see the local REC webpage for specific details). The pathway for review will depend on whether it is a student or staff project.

6.2.1 Student-led Projects

With normal supervisory support, the student will complete the application, develop and upload the relevant attachments. Then the supervisor must complete the associated declaration in REAMS for the submission to proceed. If the student is working on a project that has another person as PI (i.e., not the student) (see Section 2), the PI must complete the associated declaration on the ethics application before it can be submitted.

Once the application is submitted, it will be routed to the supervisor (primary supervisor), for ethical review. The supervisor will review the project, to ensure that it meets the criteria for Level 1 review and adheres to the ethical

standards defined by the College. The student will then receive the decision of the supervisor: approval, minor corrections, major corrections or reject (see Section 5) and feedback if applicable. If required, the student will revise the application based on the feedback and then resubmit. The application with receive additional review via REAMS, until approval is granted by the supervisor (see Figure 2).

Students, particularly post graduate students who intend to have their work published externally, should select the expedited route from the outset. Applications that route to Level 1, that are reviewed solely by the supervisor **cannot state that they have ethical approval.** However, they may use/adapt the following in their thesis – The project characteristics were deemed to be very low risk project by the Trinity College ethics system, by virtue of the fact that low risk methods were used, no personal data was collected, no vulnerable groups data were assessed, or no intrusive topics were examined. Student applicants could adapt Table 1, the column on very low risk methods and add additional details to indicate how their project met these criteria to insert in their theses appendices, to facilitate examiners in particular to know this detail.

If the application does not meet the requirements for Level 1 review it will automatically be routed to the appropriate Level 2 or 3 REC.

6.2.2 Staff-led Projects

Academic staff who plan to conduct research that meets the criteria for Level 1 review, will complete the application, and upload the relevant attachments. If the staff member is working on a project that has a that has another person as PI (see Section 2) the PI must complete the associated declaration before it can be submitted. The staff member then has two choices:

1. Choose to review their own project and self-declare that the application meets the criteria for Level 1 review and the ethical standards defined by the college. Applicants who choose to exercise this option should consider that such self-assessment, rather than review by a REC constituted in accordance with Trinity College regulations, may not prove to be acceptable to journals or granting agencies.
2. Choose to have the application reviewed by the appropriate Level 2 ethics committee to which it will then be automatically routed. **This is the recommended option should applicants wish to attest that their application was reviewed formally by a Trinity College REC** (See Figure 2). Applications that route to Level 1 and are reviewed solely by the supervisor in the case of student projects or assessed only by the applicant in the case of staff projects **cannot state that they have ethical approval.** However, they may use/adapt the following in their publications – The project characteristics were deemed to be very low risk project by the Trinity College ethics system, by virtue of the fact that low risk methods were used, no personal data was collected, no vulnerable groups data were assessed, or no intrusive topics were examined.

Note if the application does not meet the requirements for Level 1 review it will be automatically routed to the appropriate Level 2 or 3 ethics committee.

6.3 Expedited review Level 2&3

When a project is routed to either Level 2 or 3 and utilises any of the following, it will be directed to the expedited pathway of the relevant research ethics committee (see table 1 a and b also):

Human studies

- Anonymous Surveys see Data Protection Handbook
- Audits of standard practices or tests (see *Guidance audits*)
- Data extraction of publicly or non - publicly available information /documents (see *Guidance Publicly available data*)
- Quality assurance studies (see *Guidance standard audits*)
- Unrecorded and anonymous observation of individuals in public areas
- Projects that have received ethics approval from other ethics committees

Animal studies

- Translocations of large numbers of individuals of a native species or from further than they can travel naturally, or of non-native species.
- Capture and removal of wild vertebrates, under licence from the relevant specialist body, or those deemed vermin.
- Brief (less than a 2 hours) capture of small numbers (as a proportion of the local population) of wild vertebrates and return to their original site of capture.

If a project meets the criteria for expediting, it can be submitted on any date during term and reviewed in line with local procedures for Level 1 and expedited research. Previously this form of review may have been referred to as "fast tracked" or "chair approval". This remains a rigorous review process, which demands a level of scrutiny of ethical and data protection processes equivalent to that provided by committee review. If it is determined that an application originally eligible of expedited review requires major revisions, it will be rerouted for committee review, and processed along with other applications received in advance of the next submission deadline.

6.4 Committee review Level 2&3

Projects that use higher risk methods than those listed above in 6.3, will be processed in accordance with the relevant REC schedules and procedures. These can be found on the local REC websites.

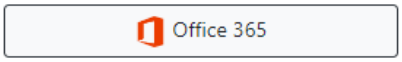
7. Guidance for completion of the ethics submission

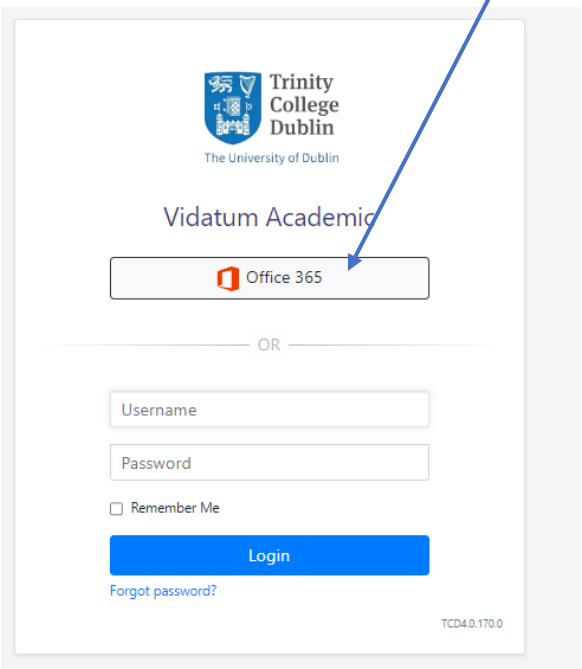
This section is made up of two parts: an explanation of how to log onto to the system, followed by a detailed description of each of the sections that may appear in the course of generating an application. Please note that, depending on the characteristics of your project, some of these sections may not be present as you complete your application.

7.3. Introduction to the REAMS system

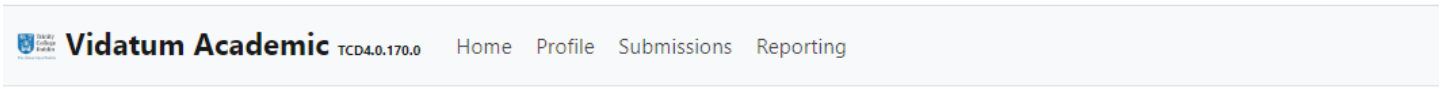
7.1.1 Sign in and outline of early pages

The web address for the online systems is https://www.tcd.ie/research/support/ethics-approval.php when you open this the screen below will appear. Log onto the system using the Office 365 button

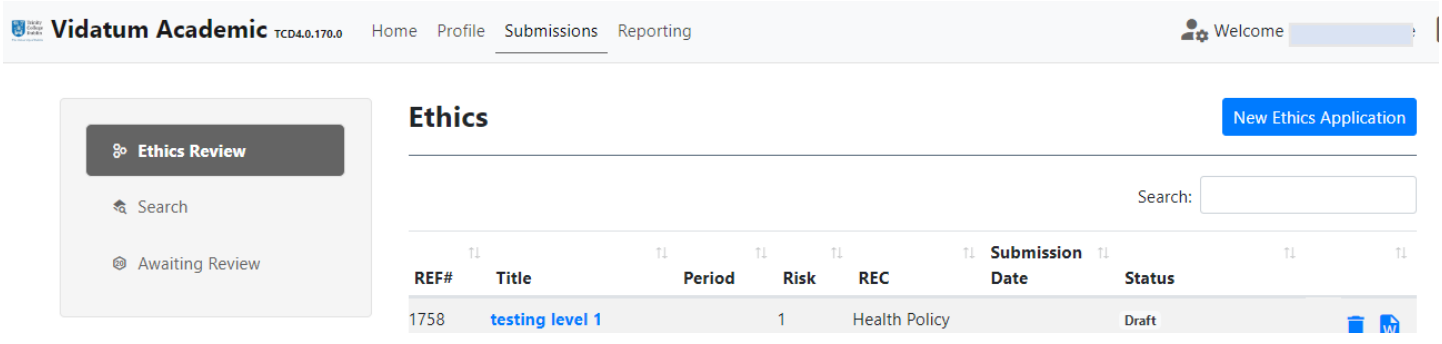




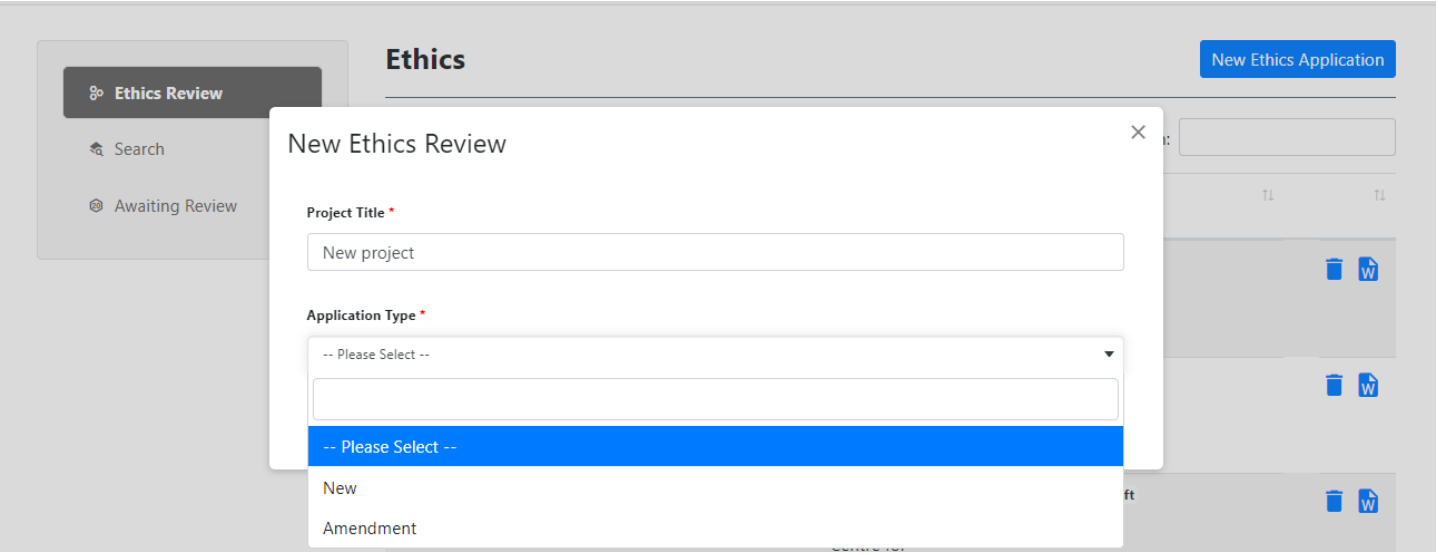
The following screen will then appear will be the home screen with your name and college details, any notifications or tasks that you have from previous or current submissions and the following leading tab.



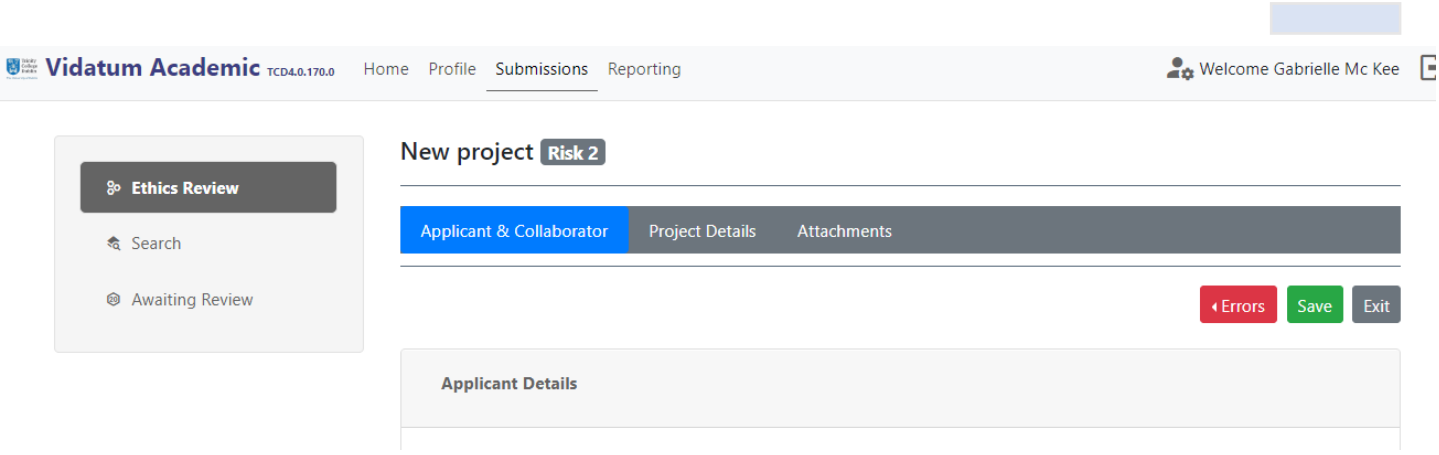
Chick on the submissions tab and the following will appear



Click in the new submissions button and the following screen will appear



Once you have submitted the pop up screen the following main screen will appear. Under this tab line is the name of the project you have just entered and the risk level it is currently classed as. The risk level may change as you answer the questions in the application form. When you complete the project details page the final level will be displayed. You should refer to this to ascertain which level of ethics committee you will be applying to so that as soon as possible you can determine which ethic committee your application will be routed to and check their local pages for further detail, including schedule of receipt of applications.



The system automatically opens on the applicant and collaborator page. In this tab currently there are three tabs appearing, as you complete the project details pages other tabs applicable to your project appear. The rest of this section details the question and guidance relating to them for each of these tabs.

7.2 Applicant and Collaborators

At the top and bottom of every page there is a save button that will allow you to save any data you have completed on that page at that time.

7.2.1 Applicant details

Applicant name

As the applicant you will be the primary contact for communications about this application. Start typing in your name, and a list will appear with your name. When you select your name other details from your Trinity records will be automatically entered for some of the questions below

Is the applicant applying as a member of the staff or as a student?

- Staff
- Student

Staff/ Student number *(autofill)*

Email address *(autofill)*

Applicants need to use their Trinity email address to apply for ethics approval in Trinity

School / Department *(autofill)*

The answer to this question is one of the characteristics used to route the application to the correct REC.

Note for applicants who belong to a centre that has a REC, please search for that centre if this is the appropriate REC for your application i.e., Centre of global Health, Centre for Health Policy and Management

Role on the Project *(drop down menu select one)*

- Principal Investigator
- Non Principal investigator
- Other

See *Guidance: Role in Project* to correctly describe your role. If you are not the PI of the project the PI will also be asked to approve the project before submission.

Primary Employer (if not TCD): *(Text field)*

For example, this might apply to a professor in in the Faculty of Health Sciences whose main employer is Tallaght etc. Complete only if relevant to the application.

Other affiliations (If applicable) *(Text field)*

For example, an applicant may be a Chair of a research group based outside college, and it is in this role that they are applying for ethical approval.

Course (for student applicant only) *(autofill)*

- PhD

Applicants Details

This section is required for all projects

Guidance: Role on project

Guidance: Data Protection

Guidance: Research integrity

Refer to the following documents:

Trinity Policy on Good Research Practice

Data Protection Training Module

Research Integrity in the Open Scholarship Era Training

• Master by research • Taught Masters • UG	
Part time / full time (student only) *(autofill)*	
I have read and understood Trinity Policy on Good Research Practice, Yes/No	
I have completed the Integrity module Yes/No/NA Applicants who are undertaking animal studies may choose NA. Staff and non-PhD students may access the Epigeum Research Integrity Training. PhD students (except staff that are conducting PhDs) must complete the Research Integrity in the Open Scholarship Era Training so that they can answer yes to this question and facilitate a completed Research integrity certificate be uploaded. See below for links.	
I have read and completed an up to date Data Protection training module in the last 12 months Yes/No This will trigger the need to complete the Data Protection Training module and requirement that an up-to-date Data Protection Training module certificate for the applicant be uploaded.	

Guidance:Role in Project

All collaborators must have their role in the project identified. Following submission, the PI and Primary supervisor will receive notifications must tick the appropriate declaration and approve the application. Without the appropriate signatures being provided, submission of the application will not be possible. In addition, for projects that include the processing of personal data, all Trinity collaborators will be required to upload an up-to-date Data Protection Certificate. In all cases, primary supervisors must upload an up-to-date Data Protection Certificate.

Principal investigator (PI) is the term used for the person responsible for the preparation, conduct, and administration of a project and (if applicable) a corresponding research grant. In most cases (including submissions by students), the applicant will also be the PI for the project. In some large projects, the role of applicant may be delegated to another member of the research team, who is not the PI. In such cases, the PI must tick the appropriate declaration, and approve the application, as part of the REAMS submission process. Primary Supervisors: Of particular importance in the case of student application is the inclusion of the Trinity primary supervisor, who is also required to approve the application prior to submission via the REAMS. If the primary supervisor is also the PI they should select their role as Primary supervisor.

Guidance Research Integrity

When you say yes to this question, you will be required to upload the certificate of completion. With the exception of PhD students who are Trinity members of staff, or students undertaking animal research projects, PhD students **must** complete and upload certification of completion of Research Integrity in the Open Scholarship Era. If you have questions

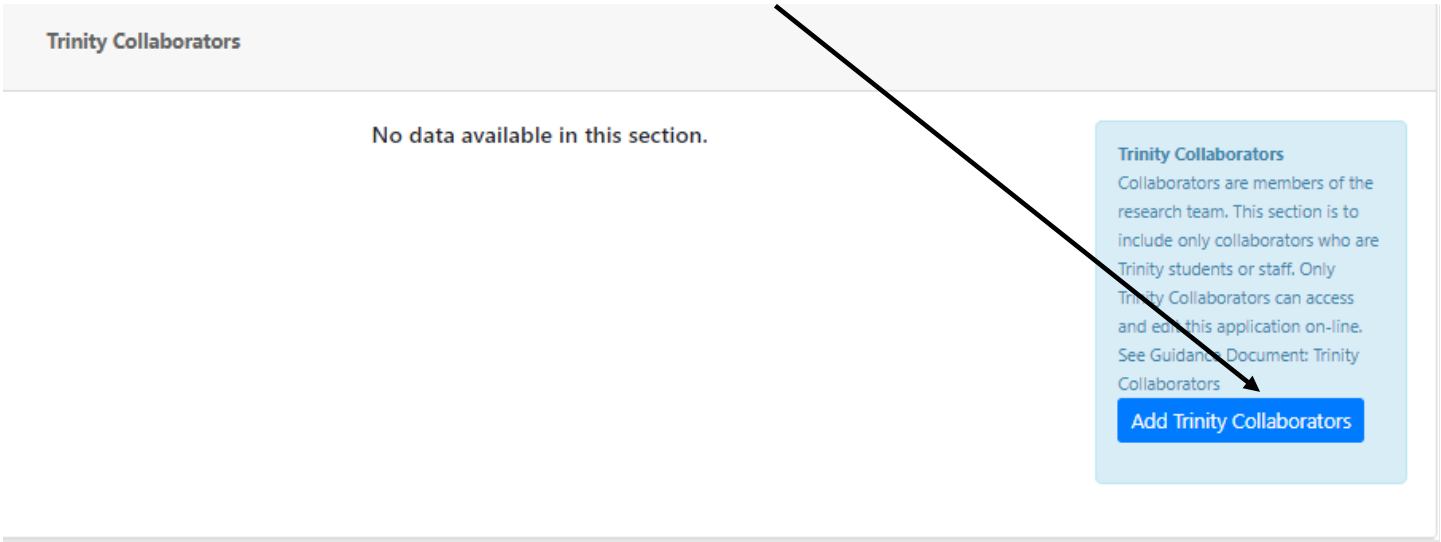
or problems enrolling in the module please contact the module coordinator, Niamh Brennan, (nbrennan@tcd.ie) or email ResearchIntegrity_CA7000@tcd.ie. For non-PhD students and staff, the Epigeum Research Integrity is available, an outline of its content and how to access it is available here.

Guidance Data Protection

The Data Protection Training Module is available on Blackboard. All applicants must complete GDPR training. The training may be accessed through the link above and in the help text. If the answer to this question is yes, you will be required to upload an attachment certifying that you have completed this training. If the applicant is a student, the designated primary supervisor must also provide evidence that they have completed the Data Protection Training Module in the past year. If a project involves the processing of personal data and generates a data protection tab, all Trinity members of the research team processing personal data will be required to complete this module. Submission of the ethics application will not be possible until all relevant certificates have been uploaded.

7.2.2 Trinity Collaborators

When you click on the Trinity Collaborators button on the left the following questions appear. When you complete the questions and submit the answers a line will appear with some of these details instead of the "No data available in the section". Click again on the add Trinity collaborators button to insert each Trinity Collaborator.



Project Role (drop down menu select one only) • Trinity Principal Investigator • Stakeholder: Academic/ Clinical/Professional/ Industrial Collaborator • Primary Supervisor • Trinity Co supervisor/s Student applications must include a Primary Trinity Supervisor in this section.	**Trinity Collaborators** Collaborators are members of the research team. This section is to include only collaborators who are Trinity students or staff. Only Trinity Collaborators can access and edit this application on-line. *Guidance: Trinity Collaborators* Add Trinity Collaborators
Name	
Email Address	
School or relevant affiliation (Text Field) If the applicant is a Stakeholder: Academic/ Clinical/Professional/ Industrial Collaborator, detail in this box after their affiliation which of these roles apply in this project.	
Title (Text Field)	

Guidance Trinity Collaborators

Collaborators is the term used here for any member of the research team including supervisors. All must be included in the application and designated as either Trinity collaborators or non-Trinity collaborators. Only Trinity collaborators can access and edit the application online. Note that, at any time, you can download the application as a PDF and forward the file to external collaborators for review. This section is for Trinity collaborators only. Collaborators based in Trinity affiliated institutions who have a Trinity ID may be entered as Trinity collaborators. This does not include individuals with "visiting" status. As per guidelines concerning the inclusion of co-authors on research publications, care must be taken to include only collaborators who will have a clearly defined role or roles on the research project. In many cases therefore, members of advisory/governance groups, for example, should not be included.

Projects that are **solely** exploratory discussions to develop a research question with an advisory group/governance group/ persons not directly used in publication or post project discussions regarding the marketing or commercialisation of the outputs of the research usually do not require ethical approval. Such explorations may however give rise to legal and reputational considerations that should be addressed elsewhere. An as example, the collection of contact details may have legal implications relating to data protection. If all processes are not sufficiently transparent reputational considerations may emerge. This may occur, for example, if the persons engaged are not made aware that they can withdraw from the process at any time.

7.2.3 Non-Trinity Collaborators

When the Add non-Trinity Collaborators button on the left is clicked the following questions appear. This step should be repeated for all non-Trinity collaborators.

<table>
<tr><td>Name</td><td rowspan="7">Non Trinity Collaborators

Collaborators are members of the research team. Non-Trinity collaborators cannot access or edit this application online.

Guidance: Non Trinity Collaborators

Guidance: Participant collaborator and participatory research

Add non-Trinity Collaborators</td></tr>
<tr><td>Email Address</td></tr>
<tr><td>Project Role (drop down men select one only)
Stakeholder: Academic/ Clinical/Professional/ Industrial Collaborator
Public or Participant Collaborator
Non Trinity Co supervisor
Principal investigator (non-Trinity)</td></tr>
<tr><td>Primary or relevant affiliation (Text Field)

If the applicant is a Stakeholder: Academic/ Clinical/Professional/ Industrial Collaborator, detail in this box after their affiliation which of these roles apply in this project.</td></tr>
<tr><td>Title (within that organisation) (Text Field)</td></tr>
<tr><td>Country (Drop down menu)

Ireland in at the top of this list for your convenience, the rest of the countries are in alphabetical order. Tick as many countries as apply.</td></tr>
</table>

Guidance: Non-Trinity Collaborators

Only Trinity collaborators can access and edit the application online. Note that at any time you can download the application and forward the file to external collaborators for review, you will have to download the attachments separately.

Include as non-Trinity collaborators, all non-Trinity co-supervisors and non-Trinity members of the research team, including international PI and collaborators as applicable. These inclusions are required especially if it is intended that such individuals will be granted access to non-anonymised data.

Under academic / clinical collaborator, you can include all other academics, clinical or professional members of the research team that that are external to Trinity.

As per guidelines concerning the inclusion of co-authors on research publications, care must be taken to include only collaborators who will have a clearly defined role or roles on the research project. In many cases therefore, members of advisory/governance groups, for example, should not be included.

Projects that are **solely** exploratory discussions to develop a research question with an advisory group/governance group/ persons or post project discussions regarding the marketing or commercialisation of the outputs of the research usually do not require ethical approval. Such explorations may however give rise to legal and reputational considerations that should be addressed elsewhere. An as example, the collection of contact details may have legal implications relating to data protection. If all processes are not sufficiently transparent reputational considerations may emerge. This may occur, for example, if the persons engaged are not made aware that they can withdraw from the process at any time.

Guidance: Participant Collaborator

Public or participant collaborators are people from the participant population or interested members of the public, who will work as collaborators during some phases of the research cycle, such as the design, analysis, dissemination, or impact of findings.

Many funded research projects now encourage the involvement of people from the participant population or from members of the public with a stake in the research. They may be involved in the design, recruitment, data gathering, analysis, dissemination or in the development of findings into policy and practice. This may be part of the methodological approach, such as in participatory action research, or it may be a condition of funding, such as PPI (Public and Patient Involvement), Engaged Research or Citizen Science. Where someone from the participant population or from members of the public has a clearly defined role or roles in the research cycle, they are part of the research team - a public or participant collaborator. When completing this ethics form, this type of collaborator may or may not have an affiliated institute /association, but the insertion of their affiliation would be informative such as an advocate from a charity or a member of a community group.

7.3 Project details

This section is to be completed by all applicants. It is key to the development of the question set for your application. Based on the information that is provided, the online form will generate – as applicable, It other sections/ tabs for completion (e.g., consent, animal research, data protection. This information will also be used to determine the assessed risk level of the project, and therefore whether the project is routed to Level 1, Level 2 or Level 3 and, within Level 2 and 3, whether the project will be sent for expedited review or committee review.

7.3.1 Main project details

This subsection appears for all projects including animal projects

Title of project *(Text field)*

This is imported from previous insertion into the system, if it needs to be changed this is the place to change it

Data collection start date *(calendar presented)*

Data collection end date *(calendar presented)*

Project end date *(calendar presented)*

Does the project involve *(drop down list)*

- Humans (or their data)
- Animals

If "animals" is selected the following two questions will appear and the remainder of this section will not. An animal research designator will also be inserted.

If "humans" (or their data) is selected the following two animal question will not appear and the rest of this section will.

Does the project animal involve - *(Drop down menu, select one only)*

1. Research in the laboratory setting that involves vertebrate animals (including foetal forms of mammals beyond two thirds of their development in utero) and cephalopods.
2. Very low risk wildlife and ecology project
3. Category 1: Low risk wildlife and ecology projects
4. Category 2: Low risk wildlife and ecology projects
5. Moderate risk wildlife and ecology projects

The following question will appear if option 1 above is selected

Is the AREC project a first application or an amendment?

- First application
- Amendment
- Not applicable

Is the research wholly an analysis of legal judgments/cases/statutes/legal provisions which have been made public by a judicial process? Yes /No

This question applies to applicants form the School of Law only, all other applicants should answer no.

Answering yes to this question facilitates automatic routing to Level 1.

Main Project Details

This section is required in all projects. Read the guidance document carefully when completing this section.

With regards to the question does the project involve 1) humans or their data or 2) animals, if you are unable to answer yes to either of these categories, your project may not require ethics approval. If you are a student discuss this with your supervisor. Please note that if this question is not answered, it will be picked up by the system and submission of the application will not be possible.

Guidance: Start dates

Guidance: Writing Phase

Guidance: Deception research

Guidance: Intrusive, harmful or may endanger humans

Guidance: Dual purpose research that could be misdirected to do harm

Guidance: Aims and objective (s) and summary

Guidance: Research in a foreign country

https://www.tcd.ie/estatesandfacilities/shared-admin-and-support/insurance/

https://www.dfa.ie/travel/travel-advice/

Guidance: Invasive and non-invasive descriptions.

Guidance: Funding

Guidance: animal research projects: please refer to the guidance to obtain further information on the projects that fit under these categories

Guidance application to AREC

Are Trinity Researchers ***only*** involved in the writing phase and/or the analysis of anonymised data for this project that has approval from an external ethics committee. Yes / No Answering yes to this question facilitates automatic routing to Level 1.	
Could the research have detrimental legal, economic or social consequences for either the participants or their establishments. Yes/ No Answering yes to this question facilitates automatic routing to Level 3.	
Intentions of study: Does the project: *(Multiselect available, you can choose more than one if applicable)* • Involve Deception • Intend to uncover additional illegal activity • Explore a topic that is potentially intrusive or is research that is harmful or may endanger the human participants • Have a military role • Have a dual purpose that could be misdirected to do harm • None of the above Unless the item "none of the above" is selected this question will route this project to Level 3 committees	
State research aim(s) and objective(s), research question or hypothesis. Word limit :100 words	
Lay Summary: including background /rationale/ justification, research approach, study design (exclude detail of measurement instruments and intervention and analysis (if applicable) (Word limit :250 words) *(Text field)*	
Identify all countries where data is collected or processed *(Drop down menu)* If some or all of your research is taking place in a foreign country, please be aware that you are not insured to travel to countries that are on the Department of foreign affairs travel list. For convenience Ireland is on the top of the list, after that they are in alphabetical order so just start writing the name of the country and it will automatically come up.	
Does the project involve: *(select one only)*	

1. Human participants and /or their data and no biological samples 2. Human biological samples not from patients taken in a non-invasive manner 3. Human biological samples from patients 4. Human biological samples taken in an invasive manner 5. Human biological samples of any size or type that could have an impact upon future treatment (e.g., human DNA sequencing) If you cannot select an answer to this question consult guidance as to what study types require ethics. Answers 3-5 will facilitate routing to Level 3. Answers 2-5 will facilitate the generation of the Human Biological Sample tab	
Is the project funded? Yes/No This question facilitates generation of a funding tab	

Guidance start dates

If you are collecting data from multiple sites, enter the earliest start date and the latest possible end date for all sites. To allow time for minor corrections before approval is granted it is generally recommended that data collection is not scheduled to begin until at least six weeks after submission to the REC meeting. Note a start date before submission date will generate an error.

Guidance Deception Research

In some specialist areas, to collect meaningful data the participant will not - at the time of recruitment, be made aware of the true aim of the study. This practice conflicts with general ethical principles and with the right to information under data protection law. Therefore, the nature of the debriefing of the research participants, and the means by which informed consent for the obscured aspect of the procedure will be obtained, are among the measures that will be assessed in the course of review. They must therefore be included as part of the ethics application. Projects that use methods of deception can range from relatively low risk to very high risk. In all cases, they are reviewed at Level 3 RECs and only by certain Research Ethics Committees.

Guidance: potentially intrusive or harmful

While all research is intrusive to some degree, intrusive topics are likely to cause risk or discomfort greater than that usually encountered during daily life. The inclusion of such topics therefore increases the risk to participants. Examples of topics that would be considered as intrusive include, but are not limited to, abortion, abuse, animal abuse, bankruptcy,

bullying, child abuse, gun control, self-harm, trauma, whistleblowing. Projects that explore intrusive topics will be routed to Level 3 RECs.

Harmful Research means research that has the potential to harm or endanger the participants, and/or researchers, and/or 3rd parties, and/or the environment. Research of this nature will be routed to Level 3.

Guidance: Dual Purpose

It is assumed that research at Trinity is undertaken exclusively for civil application and never undertaken with the intention to do harm. However, it is recognised that on rare occasions research may be undertaken that has the potential for dual purpose use in both civil and military applications. Where a dual purpose is identified there exists the possibility that the research could be misdirected to do harm.

Projects with a dual purpose that could be misdirected to do harm will be routed to a Level 3 REC. In addition, if your project is of dual use your application will need to be reviewed by the Risk Officer and Secretary's Office to determine if it is dual use research within the meaning of the EU Dual Use Regulation and to determine whether an export licence is required.

- It is important to note that the dual-purpose of the research may arise at any stage of the research process, in any possible form (e.g., microbial, devices, data, software and technology, hard-copy or electronic forms of data, dissemination, publication, presentation, communication and collaboration in which research results are made available to people other than the authors (this list is not exclusive).
- If your research potentially fits the above definition, please consult the following website so that you can use the appropriate detail for this application see *Annex 1 of Council Regulation (EC) 428/2009. [Link https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32009R0428]*

Guidance: research in a foreign country

If you are conducting research in a foreign country, please ensure that you adhere to site data protection requirements, correct data transfer and sharing procedures and the equivalent of site Garda vetting etc. if applicable.

Guidance: aims and objectives

There should be an obvious connection between the aims and objectives and the methods used.

Guidance Summary:

Rationale/ justification: How does the research relate to the current literature, gaps in current literature, any previous work?

Research approach/ Study design: In this context use research approach to outline the instruments (i.e., questionnaires), techniques or processes that will be used in the collection of data in general, such as anonymous survey, face to face interview, focus group, observation, intervention, data taken from other sources (data extraction) etc. Depending on the study, it may also be necessary to outline key study design features, e.g., will it be a survey, a trial, a longitudinal study with information collected before and after a test or intervention (exclude detail of measurement instruments and intervention and analysis (if applicable), as this information can be provided in response to a later question). If applicable, this content will be exported, to the PIL for subsequent adaption.

Guidance: Fundings

Funding refers to all types of financial support including charitable, philanthropic, government based, industry, local i.e., school / college funding etc. In the event that you secure further funding subsequent to ethics approval being granted, you must inform the approving ethics committee by submitting an Amendment.

Guidance: Invasive and non-invasive

There are thousands of different types of invasive procedures - whereby purposeful/deliberate access to the body takes place, that go beyond simple contact with the outer surface of the body. These include incision and procedures such as ionising radiation to surgery and encompass the collection of fluid and tissue samples from the body. All levels of sampling have risks and standard precautions in accordance with recognised "best practice" must be used.

Procedures can be classified using three main criteria (1) method of access to the body, (2) instrumentation, and (3) requirement for operator skill. If the relevant precautions are taken and best practice procedures are implemented, pinprick micro-sampling for blood may in some circumstances be considered, from an ethical perspective, a minimally /non-invasive procedure. Depending on the other characteristics of the project, projects utilising this technique may be assessed as low-risk (Level 2 routing). Note that not all Level 2 committees review applications that involves the collection of human biological samples. Please ask your local Level 2 committee whether this applies. Other minimally or non-invasive procedures include the transfer of insignificant energy across the skin i.e., electrocardiogram (ECG), electroencephalography (EEG), electromyography (EMG), or the taking samples of hair, mucus saliva, urine, etc. Depending on the other characteristics of the project, the utilisation of non-invasive procedures to take samples from participants who are not patients, may permit an application to be routed to a Level 2 Research Ethics Committees.

Projects that subject patients to non-invasive procedures or any person to invasive procedures, are routed to Level 3 RECs.

Guidance: Writing Phase

Projects that fulfil this criteria will be routed to Level 1, move to declaration section. You will be required to append the ethics application that was granted approval by the relevant authority, the letter of approval, and all related appendices, bundled together as an attachment.

Guidance: Animal research projects

1. **Research in the laboratory setting that involves vertebrate animals (including foetal forms of mammals beyond two thirds of their development in utero) and cephalopods**. Projects that fall under this category will be routed to the animal research ethics committee (AREC).

2. **Very low risk wildlife and ecology projects**: these projects will be routed to Level 1 and if student projects will be reviewed by the supervisor
    a. Sampling sustainable numbers from populations of invertebrate subjects (other than cephalopods), irrespective of subsequent processes.
    b. Observations of vertebrate subjects left undisturbed in their natural environment.
    c. Non-destructive measurement or observation of wild / managed environments
    d. Translocations of small numbers (compared to local population sizes) of individuals of a native species between sites all within the local area.

3. **Category 1: Low risk wildlife and ecology projects.** These projects will be routed to the School of Natural Sciences REC as they are low risk, they will take the expedited review route.
    a. Translocations of large numbers of individuals of a native species or from further than they can travel naturally, or of non-native species.
    b. Capture and removal of wild vertebrates, under licence from the relevant specialist body, or those deemed vermin.
    c. Brief (less than a 2 hours) capture of small numbers (as a proportion of the local population) of wild vertebrates and return to their original site of capture.

4. **Category 2: Low risk wildlife and ecology projects.** These projects will be routed to the School of Natural Sciences REC as they are slightly higher risk than Category 1 they will take the committee review route.
    a. Capture and removal of wild vertebrates without licence from the relevant specialist body.

Translocations of large numbers of individuals of a native species or from further than they can travel naturally, or of non-native species.

7.3.2 Details on human data and collection

This subsection will appear for most projects that involve the collection of human data, with the exception a cases in which there is an answer "yes" to either of the following questions:

- Is the research wholly an analysis of legal judgments/cases/statutes/legal provisions which have been made public by a judicial process?
- Are Trinity Researchers ***only*** involved in the writing phase and/or the analysis of anonymised data for this project, which already has ethical approval from an appropriate external ethics committee?

Is your study a mixed methods study?	**Details on Human Data and Collection** *Guidance: Mixed methods* *Guidance: Data sources* *Guidance: Publicly available data* Research data are the data required to meet the aims and objectives of the study. If primary sources are selected a draft participant information leaflet will be generated for development. *Guidance: Consent* Link to consent templates *Guidance: Health Research* If your research is Health Research you must use the explicate consent template, unless one of the exceptions for its use are met, see Health Research section. If paying participants refer Gift Voucher Policy. *Guidance: Health Research*. *Guidance: Personal data* *Guidance: Directly and indirectly identifiable data* *Guidance: Data retention* *Guidance Risk of Vulnerability* *Guidance: Healthy participants in a health trial* *Guidance: Dependant relationship* Policy on Good Research Practice Staff and students of Trinity as participants
Does the project use data from: *(select one only)* • Primary sources only • Both primary sources and secondary sources • Secondary sources only *The following question will only appear if the answer secondary data is being collected*	
Will you obtain consent from participants for their participation and for the use of their data? In the case of children – consent from a parent / legal guardian. In the case of adults who lack capacity - consent from a proxy. Yes/No If no, provide further information *If the answer to this question is yes, this will add consent form as a required attachment of a consent form and the insertion of a consent section.*	
Will payment be made to research participants? • YES – standard gratuity with or without expenses • YES - receives a gratuity in excess of standard with or without expenses • No If yes, receives a gratuity in excess an additional box will be inserted: Provide further information	
Is the project Health Research as defined by the health regulations? Yes/No If answer to health is yes generate next question	
Does the project require a consent declaration form as defined by the Health Research Regulations 2018 and amendment 2021? Yes /No	
Could any of the research data directly identify any participant? Yes/No Note this question only applies to research data see question below for other project information that has personal information	

Answer yes to having directly or indirectly identifiable data the project **cannot be** routed to Level 1 and a data protection section will be generated	
Could any of the research data directly identify any participant? Note this question only applies to research data see question below for other project information that has personal information. Answer yes to having directly or indirectly identifiable data the project **cannot be** routed to Level 1 and a data protection section will be generated.	
Do you process personal data for study administration purposes? e.g., contacting individuals or obtaining consent from participant. Yes/ No If answer is yes an additional text box will appear: Outline how you will store the information, keep it confidential, and destroy it in line with the data retention policy. Answer yes to this question and the project **cannot be** routed to Level 1.	
Which of the following best describes the general characteristics of the target population? *(Multiselect you may choose more than one)* a. Adults currently not at risk of vulnerability b. Adults at risk of vulnerability c. Children (<18 years) d. Participants with a dependant relationship with the researcher e. Staff of Trinity f. Students of Trinity If answer is b-d the project will be routed to Level 3 ethics committees. If E & F are selected this will add the required permissions as a required attachment.	
This question will only appear if your answer to is your research health research is yes. Do any of the following describe the characteristics of the target population? *(Select only one)* ▪ participants recruited because of a medical condition or treatment ▪ participants recruited because of a non-medical condition or treatment ▪ healthy participants e.g., those used in the control arm of a health trial study ▪ Other If other is selected an additional text box will appear: Please Describe	

List the inclusion/ exclusion criteria for selection of project participants *(text field)* Inclusion / exclusion criteria will be exported into the PIL (if applicable), where you can adapt it so that participants can identify why they are included in the project.	

Guidance data source

Definition of research data:

> "Research data are data that are used as primary sources to support technical or scientific enquiry, research, scholarship, or artistic activity, and that are used as evidence in the research process and/or are commonly accepted in the research community as necessary to validate research findings and results. All other digital and non-digital content have the potential of becoming research data. Research data may be experimental data, observational data, operational data, third party data, public sector data, monitoring data, processed data, or repurposed data"

In the present context research data are the data required to meet the aims and objectives of the project. These may include personal data that fall within the scope of GDPR (for further definition please consult Data Protection Guidance). Other project information such as consent forms or contact details, may also contain personal data and therefore be subject to the GDPR.

Research data are generally categorised in two ways: primary data and secondary data: Primary data are data collected directly from participants by the researcher or by a member of the research team, specifically for the purposes of the project. Means of data collection might include, for example, the use of a questionnaire or questionnaires, an interview, a photograph, an observation, an audio or video recording. Secondary data are data that have been collected for a different purpose, and in most cases by a different person or persons, which are re-used for the project. Common examples of secondary data are students' exam results, patient data, professional profile data. Some projects use both primary and secondary data. For example, participants are interviewed, and information concerning that participants is also extracted from their public profiles and privately held records.

Both primary and secondary data may contain personal data and may therefore be subject to GDPR.

Projects that use secondary data may require ethical approval, even if it is the case that the secondary data are publicly available.

Guidance: secondary analysis

Can be defined as the re-analysis of data that were collected by another person for a separate or different purpose, perhaps when addressing a distinct research question. The secondary use of data is similar to secondary analysis. It is characterised by the re-analysis of data that have already been collected by the investigator, for a purpose separate or distinct from that which was originally define, including the intent to address a different research question.

The secondary use and secondary analysis of data can give rise to ethical issues relating to informed consent. Specifically, the secondary use or analysis of data may extend beyond the originally specified purpose of the research/ data collection – to which participants gave consent. The consent given by participants must explicitly allow for secondary use and/or secondary analysis. There may also be data protection implications arising from secondary use and/or secondary analysis, that were not anticipated at the time the participants gave consent.

The reuse of data has many advantages, and many research funders now commonly require data to be archived and made publicly accessible. To be suitable, and subsequently made available for secondary analysis therefore, data need to be collected, stored, and accessed in a manner that is ethically and lawfully appropriate.
The ethical risk associated with the secondary use and/or analysis of data ranges from low risk in projects which use anonymous, and/or quantitative data that concerns non-intrusive topics, to high-risk projects such as qualitative studies on intrusive topics or projects which use personal or sensitive data. Depending on the nature of the original ethical approval, and the consent given by the (human) participants, projects that will use data for a purpose other than originally specified, may require subsequent ethical approval. Consult your supervisor and/ or local research ethics committee to discuss any such considerations before making an application.

Guidance: Publicly Available Data

More than ever within a digital and Open Research Environment (section 5.8 Data sharing Policy for Good Research Practice), researchers can access data collected by others. Overtly public data can be obtained directly, without permission or licence. Such data may include information concerning public figures, derived from blogs or other digital sources. As such data will usually have been collected for a different purpose, their use may constitute secondary analysis. Researchers should not assume that they can or should undertake analysis of such data, as they are not the owner of the data and may not have permission for the data to be used in research. While the risk associated with this type of research is likely to be low, it must nonetheless be assessed, and ethical approval may be required. Relevant considerations are the category of researcher (student or staff) and the level of risk. For example, the research may relate to an intrusive topic or concern vulnerable persons (see Secondary analysis).

Guidance: directly or indirectly identifiable data:

If there is a possibility that the data could, directly or indirectly, identify individual living persons, there is a legal requirement to notify the DPO of the intended use (see personal data).

These points also apply to other publicly available data, including databases, which can be assessed by permission, by default - because you are a member of an association, or by licence. Ethical approval may not be necessary in many instances, such as when the project proposed is consistent with the aims and objectives of the original research that generated the data. In other cases, however, ethical approval will be required (see Secondary analysis).

Guidance: consent

Informed consent: This is the process whereby competent potential participants are given information about a project (Participant Information Leaflet) sufficient to make a choice as to whether they wish to participate or not. After receiving the information concerning the project, a potential participant is usually given at least seven days before they are asked to give their consent to partake in the study. Any proposed deviation from this timeframe must be justified within the ethics application. These two phases - the information-giving process and the consent-gathering process, make up the informed consent process. In studies that recruit human participants, consent must always be recorded. It is best practice that consent is written. The consent form should be signed by the participant and countersigned by the researcher (with a copy being held by the researcher). In some limited circumstances, such as in the administration of anonymous surveys, consent may be indicated by ticking a single box. More usually a more expansive tick list is provided. In projects that meet the definition of “health research”, it is legal requirement that a specific form of consent is obtained. This is termed “explicit consent” (see also consent declaration below).

Guidance: explicit consent

If the project meets the definition of "health research" (see *Guidance Health research* below) as provided by the Health Research Regulations 2018 (amended 22nd January 2021), explicit consent must be obtained. Please note that "health research" is defined broadly within the Health Research Regulations. Consequentially, a wide range of research activity is subject to the Regulations and entails the requirement for explicit consent. As the term implies, explicit consent requires that the information provided is explicit, in that there is no room for misinterpretation, and that the participant must give an express statement of consent. In explicit consent it is a requirement to specify the data to be processed, to explain the purpose of processing this data, and detail the risks involved due to the data processing (further detail or link to elsewhere needed).

Proxy consent: This is required when the participant is a child, or and in some cases in which the participant is an individual at risk of vulnerability. A Child is defined in the Children's act 2001 (amended) as "a person under the age of 18 years". Adults at risk of vulnerability may be able to give their consent unaided, may be able to give their consent with support or, in some cases, may not be able to give their own consent.

Any research undertaken with participants who are children (or using data obtained from children), or with participants who are persons at risk of vulnerability (or data obtained from such persons) who cannot consent themselves, requires proxy consent – that is consent given on their behalf by a parent or guardian.

In addition to proxy consent, assent from the participant is required if the child/adult is competent/ to give assent. Even if consent has been successfully acquired from the parent/legal guardian, if the children/ persons are able and do not give their assent, they must not take part in the project.

The Participant Information Leaflet must be drafted to be suitable for the age / capacity of the participants, using instruments such as the Flesch-Kincaid readability tests, SMOG Readability Index or review by the National Adult Literacy Association are some of the methods that can be used to address this. It must adequately inform prospective participants about the goals of the project, what participation will involve for them, and the way in which they can withdraw their consent and cease participation.

Guidance: Health Research

Is defined in Regulation 2 of the Health Research Regulations (as amended) as:

- Research with the goal of understanding normal and abnormal functioning, at the molecular, cellular, organ system, and whole-body levels.
- Research that is specifically concerned with innovative strategies, devices, products, or services for the diagnosis, treatment, or prevention of human disease or injury.
- Research with the goal of improving the diagnosis and treatment (including the rehabilitation and palliation) of human disease and injury and of improving the health and quality of life of individuals.
- Research with the goal of improving the efficiency and effectiveness of health professionals and the health care system.
- Research with the goal of improving the health of the population or of defined sub-populations through a better understanding of the ways in which social, cultural, environmental, occupational, and economic factors determine health status

- Research with the goal of improving the health of the population as a whole or any part of the population through a better understanding of the ways in which social, cultural, environmental, occupational, and economic factors determine health status.
- Shall include action taken by the controller that has obtained the personal data to establish whether an individual may be suitable or eligible for inclusion in the research and such action shall not require explicit consent or ethical approval by a research ethics committee where such action is……. carried out by a health care practitioner or person studying to be a healthcare practitioner or an employee of the controller who would ordinarily have access to the data or an authorised person (as defined in the amendments)

Guidance Data Retention

Information on the length of time for which personal data gathered as part of the **project data,** and/or in **other project information,** are to be retained, must be indicated in the Participant Information Leaflet. Researchers should consider all potential project information and not just primary sourced data, for example, contact details and signed consent forms constitute personal data. Information on data retention is available in the Policy for Good Research Practice and the Data Protection Handbook. Trinity also has a detailed Data Management policy and a Data Retention Schedule,(see page 5 for research). The material below these sources of information with particular emphasis on retention of project data and other project information that contains personal data. The retention of project data that has personal information will be addressed in the data protection section. In the project details section applicants will have to give information on how they address retention of project information that has personal data used for administration purposes.

Guidance Personal Data

For any research using (collecting or processing) personal data, the open-access motto "*as open as possible, as closed as necessary*" is important. Personal (identifiable or coded) data must not be kept in a form that permits identification of the individual for longer than is necessary (storage limitation). As such, time limits should be established at the outset of the research project for periodic review of project information and project data, de-identification (pseudonymisation), anonymisation, archival, and/or erasure (if applicable). Once irrevocably anonymised, project data is recommended to be stored for a minimum of seven years after completion of the project (see below for further recommendation regarding data retention). In line with the principle of transparency, the retention period or the criteria used to calculate this retention period should be shared in the participation information leaflet.

How long should I retain the data collected in my project?

This determination is both project-specific and, within projects whether it is research data or other project information. The following is a non-exhaustive list of aspects to consider when calculating this period. The retention time may be different for the project data and personal data for administration purposes such as contact details and consent forms, therefore consider them separately, depending on the characteristics of the project.

If your project has project data that contains personal data it will generate a data protection section in this application that will request details of the personal data, data retention, anonymisation, or destruction/ erasure of personal data and the rationale for these, an outline of this is also required in the Participant Information Leaflet so that the participants know when their personal data will be destroyed.

The timing of the destruction of project data personal data can have implications for participants, such as when they can request withdrawal of their personal data i.e., when the data is anonymised and codes destroyed, these data cannot be withdrawn, and the participant should be aware of this.

The following are minimum data retention periods that are recommended for project data and information in general, and below some further recommendations as to what would be good practice to fulfil the GDPR guideline regarding minimum retention time of personal data and the protection of participants. Anonymous data can be retained indefinitely.

1. For legal and regulatory reasons (medical or professional negligence, audit, etc.) – the recommendation is for the duration of study plus 7 years after completion of project. This is so that the participant can have legal redress if there are adverse effects of being in the project.
2. For evidence reasons – i.e., novel IP, etc, retain indefinitely.
3. For compliance with funding body – e.g., retain for the time requested by funder.
4. To meet requirements of research contracts – retain for the time specified in the contract.
5. For academic assessment i.e., Vivas and publication purposes (when verification or reanalysis, etc. is requested.) retain for the duration of the project plus 3 years.
6. Secondary use of personal data for research purposes (other than health research) - retain the minimum data required for the specific secondary use, providing that the data is kept accurate, confidential, and secure.

These timeframes do not dictate when and if the data should be anonymised.

With regard to point 1 above, this time frame should be applied to both retention and anonymisation of all data and project information, in projects that have interventions, moderate to high risk, or have the potential to cause harm. In these cases, the project data Primary /Secondary data and personal data for administration purposes, such as consent forms, codes and contact details should be kept for this period in a non-anonymised format, so that there is the potential to relate the information back to the individual in case of negligence harm etc. In these instances, the anonymisation of the projects data and some administration documents, such as consent forms and codes, should also be deferred until the end of this period.

In most other lower risk projects, and for projects t to which 2-5 apply, retention of any data in a non-anonymised format may not be as essential and therefore anonymisation of project data and destruction of other project information such as contact details, codes and consent forms that contains personal detail can be scheduled earlier to minimise the retention of personal data. Applicants should also consider whether other characteristics of their project would influence when anonymisation of the personal data occurs factors such as: how many phases are in the studies, do I need personal identifies to relate information from different sources: do I need to be able to go to participants to amend or get missing a data, how will I distribute the findings of the results to the participants.

Personal data in the form of contact details and consent can be withdrawn at any time at the participant's request. Project data whether discussion in an interview or from a database or from a questionnaire, may be withdrawn by participants before anonymisation of data or before withdrawal of data would have a significant impact on the project after data analysis in a qualitative study https://www.tcd.ie/itservices/internet/filestorage.php

Details on up to when data can be withdrawn should be included in the in the Participant Information Leaflet.

There is no stipulation that data needs to be retained in its original format. For easy storage and increased security of the data many formats and documents can be digitalised and stored in a manner compatible with Trinity storage recommendations. https://www.tcd.ie/itservices/internet/filestorage.php

Further Guidance:

1. For Data Protection Commission guidance on the principles of GDPR please see here

3. For guidance on data management. See CESSDA Data Management Expert Guide
https://www.cessda.eu/Training/Training-Resources/Library/Data-Management-Expert-Guide

4. Guidance on data anonymisation. See here

5. Data storage and sharing

If you are unclear about how long you should retain personal data, please contact your supervisor (if applicable) in the first instance, and the research DPO can be contacted for advice, with regard to the retention of project data that contains personal data at researchDPO@tcd.ie.

Guidance: Vulnerability

Whilst promoting inclusiveness, it is a key requirement of the ethical approval process that potential risks be assessed. Participants who are at risk of vulnerability are not always vulnerable; their vulnerability may change with the situation and environment; their vulnerability may change over time. For example, the nature/ topic of the research itself may influence whether a project that engages participants at risk of vulnerability would be routed to a Level 3 REC (*See Guidance and Policy for Good Research Practice).* Research policy within Trinity gives special consideration to protecting the wellbeing of individuals at risk of vulnerability. Therefore, projects from the following groups are always routed to Level 3.

Vulnerable means but is not limited to any participants from the following groups:

- Children: For the purposes of research children are anyone under the age of 18. All projects involving child participants, or their data, are routed to Level 3 REC
- Prisoners
- Asylum seekers: these are migrants that are driven from their home
- Persons who require support to give consent:
    - these may include adults with mental health illnesses, one or more learning disabilities, literacy difficulties, cognitive impairments or communication disabilities. Not all the people in these groups will require support to provide consent and where this is the case, depending on the other characteristics of the project, these projects could be routed to Level 2 (Low risk) (see below)
- Participants who have an unequal power/ dependant relationship with the researcher e.g., student/ lecturer, employee/ manager, carer clinician / person they care for unless the risks of these are mitigated against.
- Participants who have just been diagnosed with a life –limiting/threatening condition/dies or who are terminally ill

As cited above if the participants could be considered vulnerable but have capacity to provide informed consent without support, these projects could be routed to Level 2 (Low risk). Participants who may be at risk of vulnerability can be indirectly supported by ensuring that the Participant Information Leaflet is accessible for a person with their capabilities, and that they have the capacity to understand the information provided and can independently consent to participating in the project. If all of these conditions are satisfied, it may be possible for a Level 2 REC to assess the application. If these requirements cannot all be satisfied, for example, the participants will be at greater risk of vulnerability and/ or require additional support in order to partake in the project, then the project is deemed to be of higher risk and the application will be routed to Level 3.

Guidance: dependant relationship

Examples of dependant relationships include a carer/ clinician and the person they care for, an educator and a pupil, a line manager and an employee. These relationships are more likely to be open to coercion, in that an employee for example may feel they have to partake in a study undertaken by their line manager. Projects with dependant relationships are considered moderate to high risk and therefore will be routed to Level 3 research ethics committees. Projects should be developed either to avoid recruiting participants who have a dependent relationship with the researcher or to use methods that reduce the risk of coercion in recruitment. In qualitative data collection, recruiting participants with a dependent relationship should be avoided, if at all possible, strategies such as recruiting from another unit could be employed. When recruitment of participants with a dependent relationship cannot be avoided other strategies can assist such as using anonymous surveys with a moderate to large sample, ensuring the profile questions are unlikely to reveal the identity of the participants by minimising the profile data collected and /or categorising data collected i.e., using age range rather than years, or not recruiting participants directly but using posters or gatekeepers.

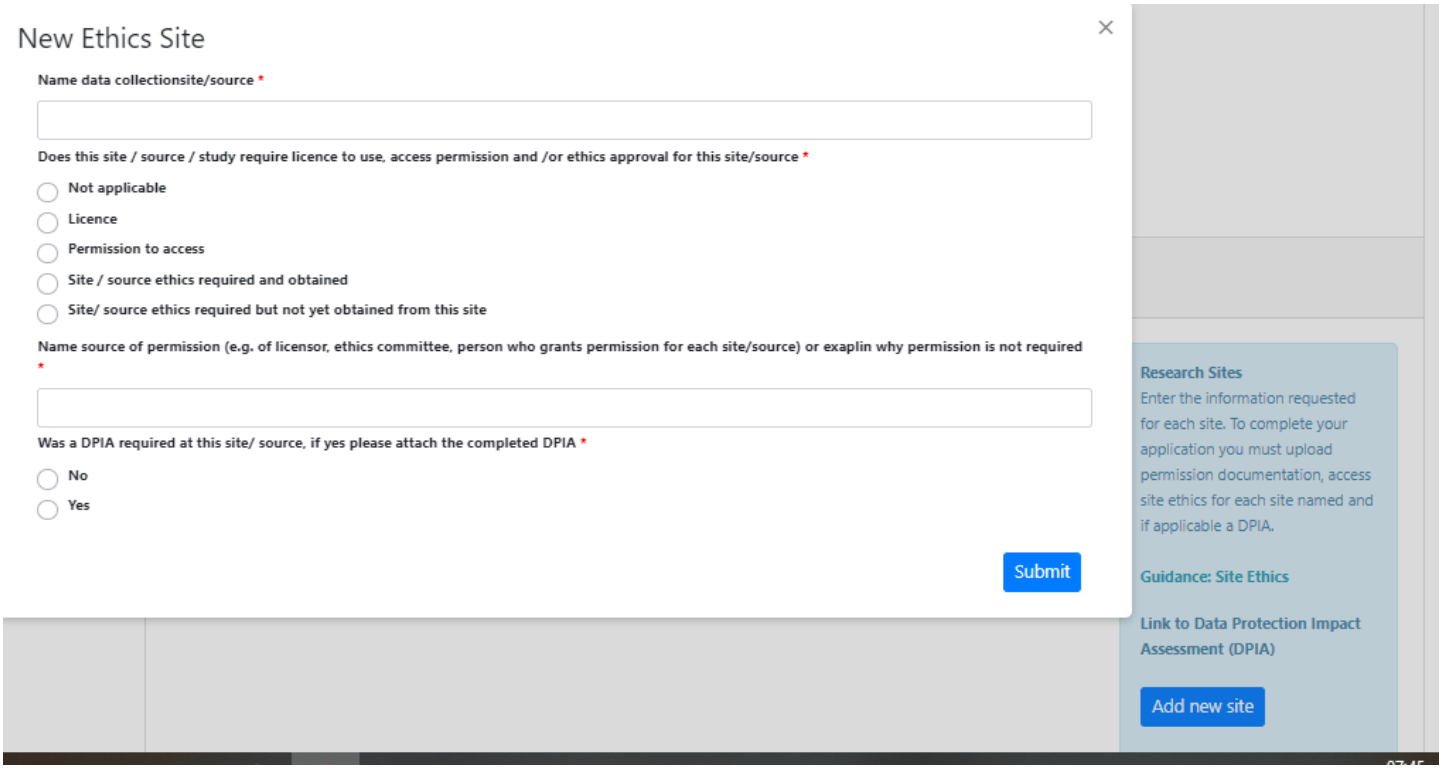
Guidance: Healthy Participants in a Health Trial

If you are conducting health research (see Guidance Health Research) the health regulations apply even if the participants are drawn from a 'healthy' population. Healthy participants are a sample of individuals recruited from the general population (e.g., through the community or a general source, not through a health-related database and or database for persons at risk of vulnerability) who are considered healthy and not at risk of vulnerability.

However, it is recognised that recruitment of a sample from the general population may unintentionally include some participants who are at risk of vulnerability. This is acceptable in most cases.

7.3.3 Research Sources and Sites

For each separate source / site of project data click in the “Add new site/ source” button in the right had column and the “New Ethics Site” box will appear as a pop up. Enter only one site/ source for each pop up box and click again on the Add new site button to add additional sites/ sources.



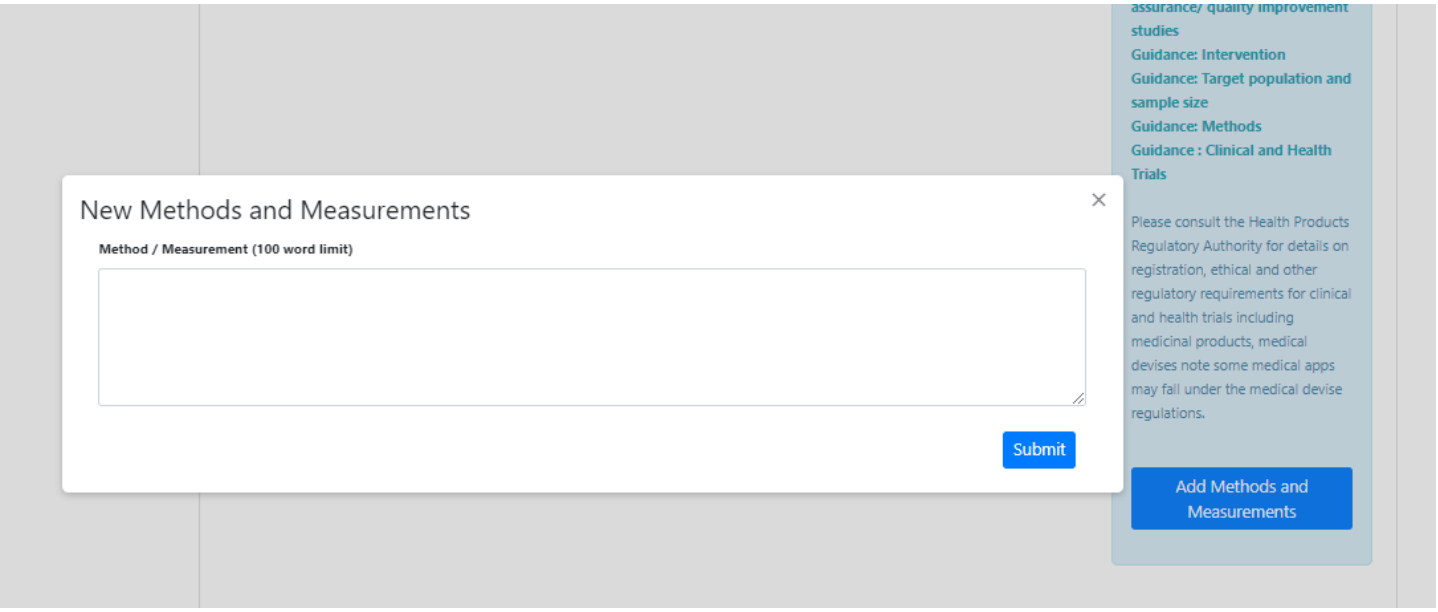
Name data collection site /source	**Research Sites and data sources** Enter the information requested for each site. To complete your application, you must upload permission documentation, access site ethics for each site named and if applicable a DPIA. *Guidance: Site Ethics* *Guidance: Low Risk methods* **Data protection Impact assessment** **Add new site / source**
Does this site / source/ study require licence to use, access permission and /or ethics approval? *(Select one)* 1. Not applicable 2. Licence 3. Permission to access 4. Site / source ethics required and obtained 5. Site/ source ethics required and not yet obtained from any site If you project requires both ethics and access, please merge these documents in the one attachment.	
Name source of permission (e.g., of licensor, ethics committee, person who grants permission etc. for each site/source) or explain why permission is not required.	
Was a DPIA required at this site/ source? Yes/No If yes, please attach the agreed/ approved external DPIA	

Guidance: site ethics:

The information required for ethical review of research is generally the same across all institutions. However, some elements of the application form may differ, and reflect the specific purposes of a particular institute. In addition, some of the information necessary for the ethical approval process may appear in other documents, such as access documents or data protection documents.

7.3.4 Outline of Project Methods

For each method/ measurement click in the "Add Methods and Measurements" button in the right had column and the "New Methods and Measurements" box will appear as a pop up. Click again on the Add Methods and Measurements button to add additional methods and measurements.



Outline the Data Collection methods For each method employed add a methods and/or measurements i.e., survey, focus group questions, blood tests In this box provide a general description of the methods you will use in your study. Be sure to mention all the methods/ measurements you will use. The add method and measurements box will allow you to describe these in more detail if needed. Each method /measurement inserted they will be added to the list of attachments required. Later in this section you will be asked about interventions (if applicable), sample size and analysis so these can be exclude detail of these from the description here.	**Methods and measurements** Outline of Project Methods Add methods and Measurements Create individual entries for each instrument, sample, measurement and test you will use. When describing the instrument of data collection, indicate if the instrument/s is currently usual practice or how it differs from usual practice (if applicable) or if completely new to the cohort being researched. i.e., student survey utilising Trinity annual student survey form with additional section of questions to evaluate new changes in practice. Interventions: Clearly indicate in your outline if this is a new intervention that is being developed and tested (both trial and non-trial projects) or a non-trial evaluation of a practice that is already in place. *Guidance: Low risk methods*
Does your project use any of the following methods **exclusively**? (*Select one only)* 1. Quality assurance studies 2. Anonymous Surveys 3. Unrecorded (audio and video) and anonymous observation of individuals in public areas 4. Audits of standard practices or tests and /or quality assurance/ quality improvement studies 5. Information, documents or data which are in the public domain	

6. A data source not publicly available but which you have permission to use 7. No If 1-4 selected this is a criteria that is needed for routing to Level 1 and is a criteria for expedited review at Level 2 or 3	*Guidance: Audits of standard practice and /or quality assurance/ quality improvement studies* *Guidance intervention:* *Guidance: target population and sample size* *Guidance: Methods* Guidance for Clinical and Health trials should consult the Health Products Regulatory Authority for details on registration, ethical and other regulatory requirements for clinical and health trials including medicinal products, medical devises note some medical apps may fall under the medical devise regulations.
Does the project include an intervention? Yes/No The following two questions will appear if you answer to the above intervention question is yes.	
Please select which of the following best describes the intervention *(select one only)* 1) Health non trial (including, psychology, social care including educational intervention) 2) Health trial (including, psychology, social care, including educational intervention) 3) Educational 4) Other	
Outline the intervention/s *(Text field)*	
What is the approximate size of the target population? *(Number)*	
What is the proposed sample size -how many participants are involved in the study? *(Number)*	
Justification for the sample size *(Text field*	
Outline the method of analysis (Word limit :100 words) (*Text field)*	

Guidance: low risk methods

Projects that select 1-4 above are deemed to be using low risk methods. This is one of the criteria used to determine whether the applications should be routed to a Level 1 ethics committee. If other project characteristics indicate that the project should be routed to a Level 2 or Level 3 Committee, the application may be considered for expedited review.

Guidance: audits of standard practice etc

The terms audit (including clinical audit) and quality improvement and quality assurance although different are often used interchangeably from an ethics point of view, as the principles that apply to them are the same.

Audits, quality improvements, or assurance projects of themselves are not research. If, however, the outputs are published either in a thesis or in another form, then they are considered as research, i.e., from an ethical perspective. As

the data are being used for a purpose different from that for which they were originally collected, there may be further ethical and legal considerations. These methods are deemed to be of relatively low risk, and when reviewed at Level 2 or Level 3 the application may be considered for expedited review (see section 5).

Guidance: methods

Two questions refer to the methods used. In the first of these, you are required to outline the data collection methods e.g., interview, survey, questionnaire, blood samples etc. In the second question you will be asked to name any specific instruments that will be used. The responses may include the names of specific questionnaires, a data extraction instrument, interview/ focus group guide, method of blood sampling, measurement tool, results of tests etc. Each of the items that is listed in response to this question will be recorded by the system. An attachment that corresponds to each instrument must then be uploaded. Submission of the application will not be permitted until all the required attachments have been uploaded. In each instance, the attached document should contain a level of detail concerning the measurement instrument sufficient to permit its adequacy to be gauged by a REC. Review the aims and objectives of the project to ensure that methods cited will achieve the desired outcomes of your project.

Guidance: Intervention

An intervention can be generally defined as a process that is imposed on all or some of the participants as part of the project. Examples include a new method of teaching, or the use of an app to record blood pressure. It is not part of usual practice but something different. If a study is evaluating a practice that has already been established, and which is not to be developed and implemented as part of this project, then it is an evaluation/ audit quality assurance study, rather than an intervention.

The system will insert into the PIL template (if applicable) entry for each test/ intervention/ experiment. The template can then be adapted appropriately for your participants. As interventions may increase the risk to the participants, all projects that answer yes to this question will be routed to a Level 3 REC.

Guidance: target population

A target population refers to the total available population at the sites/ sources from which you are collecting data that will satisfy your inclusion criteria. In contrast, the sample (or “population sample”) is the subset of the target population from whom you propose to collect data. The number of individuals in this subset constitutes the intended sample size. It may be helpful to know the size of the total eligible / target population, as it can assist in planning to ensure that the sites/ sources are sufficient to achieve the necessary sample size. Projects that concern a relatively small target population, and which require the involvement of a relatively large proportion of that population, can have implications not only for the recruitment strategy needed to achieve the required sample size. Such projects may lead to an increased likelihood of a person becoming identifiable indirectly from the profiles of individual participants. For example, among the staff in a primary school, an individual may be identifiable by virtue of being a person with a PhD. In some survey projects the target population and the sample population may be the same. In other cases, it may be hard to estimate the total target population (e.g., if an app-based intervention is made available through the Apple App store, or via a website, rather than distributed only to a limited number of schools). In all cases, consider how to mitigate against possible identification of the participants.

7.4 Sampling and recruitment

This section will be included if the applicant indicates yes using primary sources.

Outline the sampling method *(Text field)*	**Sampling and Recruitment** This section is required as you will be collecting data from primary sources *Guidance: Sampling method* *Guidance: Time commitment* *Guidance: Gatekeeper and their role* *Guidance: Recruitment*
Describe the time commitment of participants *(Text field)*	
Will the research require/use a gatekeeper? Yes/No If answer is yes, this will enable the following questions If the answer is yes to this question the following three question are also presented.	
Outline the position/role of the gatekeeper within their organisation *(Text field)*	
Detail the role of the gatekeeper in the project *(Text field)*	
Is there a dependant relationship between the gatekeeper and the participants? Yes/No If answer is yes, this will enable the next question	
Outline how this is going to be managed to mitigate against the dependencies. *(Text field)*	
Give a detailed step by step description of how participants will be recruited and append the recruitment material. *(Text field)*	

Guidance: sampling method

Detail how you will select the sample The most common simple sampling methods are convenience sampling. This involves recruiting those who meet the eligible criteria, when you or they are available and are willing to participate. The term purposeful sampling applies when you have already determined inclusion/ exclusion criteria and will be selecting subgroups that in accordance with the criteria (e.g., 50% males, or 50% physically active). The term, snowball sampling is used when you will ask participants to refer other participants to the project. Consult relevant methodological text for details of other sampling methods that may be appropriate to your study and discipline. There are specialised methods that apply particularly to trial studies.

Guidance: time commitment

In order to give consent, participants need to understand the commitment they are making. The answer you provide will be exported to the template PIL (if applicable), for you to adapt to the requirements of your participants. The response should be accurate, realistic and specific. An example might be: "You will have two questionnaires posted to you about a month apart. Each questionnaire takes about 40 minutes to complete".

Guidance: gate keeper

Some projects require gatekeepers. The role of the gatekeeper is usually to assist the researcher in the recruitment or screening of participants for the study. Gatekeepers may be individuals affiliated with a specific organisation. In this instance, their role in the project might include giving / sending letters, emails to eligible participants. One benefit of this approach is that the researchers need not have access to personal contact data. It may also serve to reduce any feeling of pressure to participate. This is particularly important if the participants have known the researcher in another role. Organisations themselves may act in a gatekeeping role by posting an email or a social media announcement about a project. As the precise role played by gatekeepers varies across disciplines and projects, you should refer to the literature that is relevant in your area, and/or consult experienced researchers. Be specific with regards to the role of the gatekeeper in relation to the project, and the position of the gatekeeper within their organisation. Will the gatekeeper be distributing flyers, posting social media advertising, handing out participant information leaflets, screening a database to select suitable potential participants and/or contacting potential participants on your behalf? Does the gatekeeper have a position of authority within the organisation or are potential participants dependent on them in any way?

Guidance: recruitment

Provide exact detail of each step in the recruitment process. Your answer should identify the who, where, how, why and when. Include practices that will help maintain the privacy of those who are and those who are not recruited. You are required to append the recruitment material i.e., email, letter or poster etc. to complete your application.

7.5 Animal Research

This section will be included if the applicant says yes to animal research

What setting/s will be used for data collection *(Multi selection select all that apply)* 1) Laboratory 2) In the wild 3) Other	**Animal Research** The Section is required because your project involves animals.
Describe the project including the taxa and species used and the sample size. *(Text field)*	
Outline the potential benefits likely to derive from the project. *(Text field)*	
Describe the impact of the research on the subjects and their environment. Describe the mitigation of these risks. *(Text field)*	
Describe any risk to the researcher of carrying out the research. Describe the mitigation of these risks. *(Text field)*	
Is this work covered by any externally held licence? Yes /No If the answer is Yes, this will add Licence to the attachments required for submission.	

7.6 Health Research

This section will be included if the applicant indicated yes to the question Health research

Please indicate which of the following applies to your health research project: • Explicit consent will be obtained • The data are irreversibly anonymized • You are carrying out a low risk, retrospective chart review • Deferred consent • You obtained informed consent prior to 8 August 2018 • A consent declaration has been/will be obtained from the Health Research Consent Declaration Committee If you are carrying out a low risk retrospective study, you will be required to attach the local site DPO approval before submission will be permitted. If you are applying or have a Consent declaration you will be required a draft completed unapproved declaration with this application before submission will be permitted.	This section is required because your research meets the definition of the Health Research Regulations 2018. Health research generally requires explicit consent unless the conditions for an exception are met. *Guidance: Health Research* *Guidance: Consent* *Guidance: Explicit Consent* *Guidance: PI and insurance* and *Consent declaration* Health Research Regulations 2018 and Health Research Regulations amendments 2021
Is the PI a medical doctor / dentist covered by the state claims agency (SCA) Clinical Indemnity Scheme (CIS) for research conducted within a designated state authority (HSE hospital or Service Provider)? Yes/ No Only required is an intervention is part of the project protocol.	
Will the project involve the administration of any substances or require participants to refrain from taking any substance? Yes/ No If yes please detail, substance, amount, desired effect, possible side effects, measures for minimising risks.	
Will there be ongoing clinical supervision of the participants by a duly insured clinical practitioner during the project? Yes/ No	
Will the research participants' General Practitioner be informed that they are taking part in the project? Yes/ No	
Will permission be sought from the research participants to disclose information (for example, information about adverse outcomes) to their GP? Yes/ No	

With respect to projects that include an intervention to be carried out within a designated state authority (HSE hospital or Service), it is usually the case that a PI who is a medical doctor/ dentist will be insured to carry out the research. Other applicants may answer no to this question.

Applicants seeking a consent declaration are required to have ethical approval in place before this can be obtained from the Health Research Consent Declaration Committee. In such cases, when all other required revisions have been completed, the outcome will be given as: minor revision approval in principle awaiting Consent Declaration. The project will be granted full approval when the consent declaration is authorised by the Health Research Consent Declaration Committee, and a copy of the corresponding letter has been received and uploaded, and then scrutinised by the REC.

7.7 Consent

This section will only be included if the applicant indicated yes to question earlier asking is consent is going to be taken

How will consent be obtained and by whom? *(Text field)*	**HELP TEXT**: This section is required because you will obtain consent from participants. Give details on how consent and/or assent are recorded, documented, stored and destroyed. *Guidance: Consent* *Guidance: Risk of vulnerability* *Guidance: Garda clearance* *Guidance: Time interval* *Guidance: Participants withdrawing from project*
Do your participants require support to give consent? Yes/No If yes, a provide further information will appear See Risk of Vulnerability for more information on support needs	
Do you require assent from participants e.g., because of their vulnerability? Yes/No If yes, a provide further information will appear.	
How will assent be obtained and by whom? *(Text field)*	
Are you required to have Garda clearance? Yes/No	
What is the time interval between giving information and securing consent? (Select one) • less than 7 days • or more days If less than 7 days a provide further information box will appear.	
Describe how you will inform participants about the use of their personal data This answer will be inserted into the draft PIL for you to adapt.	
Describe how participants can withdraw their consent and/ or their data This answer will be inserted into the draft PIL for you to adapt.	

Guidance: garda vetting

It is a legal requirement that researchers who undertake research with, or gather information from, children or vulnerable adults receive garda vetting. If this requirement applies, you will be required to append up-to-date Garda vetting documentation. It is the responsibility of the researcher/s to ensure correct and up to date garda clearance is in place. ***A new garda vetting procedure is currently being developed when available this section will be updated.***

Guidance: time interval

Seven days is the minimum recommended interval. This seven-day period is to give participants an opportunity to consider the implications of participation and consult with family, friends, or others about it. Any deviation from the recommended seven days needs to be justified.

Guidance: Participants withdrawing from project

Personal data in the form of contact details and consent can be withdrawn at any time at the participant's request. Project data, whether discussion in an interview or from a database or from a questionnaire, may be withdrawn by participants before anonymisation of data or before withdrawal of data would have a significant impact on the project after e.g., data analysis in a qualitative study, after submission of thesis. Details on up to when data can be withdrawn should be included in the in the Participant Information Leaflet.

7.8 Risk

7.8.1 Risk or harm to the researcher

After you have completed the first question the column on the left will have a button for add risk.

What setting/s will be used for data collection *(choose all that apply)* • Place of convenience for participant • Participant's place of work • Participant's home • Classroom • Hospital/clinic • Laboratory • In a foreign Country • Online • Other	**Risk to Researcher** This section is mandatory for all projects. Click on the add button below for each researcher risk. *Guidance: Risk, benefit, harm to researcher, participant, environment and society.* *Guidance: lone worker*
If other elaborate	

Enter each risk separately by submitting the first risk and selecting the add button again, if applicable.

Researcher Risk
Identify the risk from the list below • Is the topic explored potentially intrusive or harmful or may it potentially endanger the researcher? • Emotional Risks, including stress, distress, or discomfort • Physical Risks, including bodily harm, aggression, or violence • Other • None If other elaborate If none if selected the following additional question will be blocked out and the box is ready to press submission
Estimate the Impact: • Low • Medium • High
Estimate the Probability/ likelihood: • Low • Medium • High
Detail the Mitigation measures *(Text field)*

Are you a school of psychology applicant interviewing and or testing with adults or children? Yes/No This question is for School of Psychology only If the answer to this question is yes the applicant will be required to append a Declaration for Interviewing or testing adults or children	

Guidance: risk benefit harm to researcher, environment and society

This series of questions asks you to reflect on the risks to you as a researcher and more broadly to the environment and society. They encourage you to develop plans to mitigate against these risks to ensure that you and the other researchers in your team are protected. Debriefing is a common strategy used to mitigate against stress, distress or discomfort.

Be advised that you are not insured to travel to countries that are on the Department of Foreign Affairs do not travel list: see https://www.tcd.ie/estatesandfacilities/shared-admin-and-support/insurance/ and https://www.dfa.ie/travel/travel-advice/

Consider the risks of collecting the data, and also those that arise from the dissemination of findings. Consider the worst-case scenario for each risk.

One way to do this is to consider whether the data collection phase of your project, or your results of your study, *could* have a negative impact. Here are some examples. Do you have permission to reveal the site name? Are the data collected and published in a manner such that the identities of individuals involved cannot be revealed of inferred? Will permission be obtained from all vested persons/organisations? Is there any aspect of the research that has the potential to cause reputational damage to Trinity? If your previous experience is not sufficient to gauge the risks that may arise, consult with your supervisory team / colleagues, or with recognised experts in the field.

Guidance: lone worker

We must not only protect the participant but also the researcher. Lone working can be defined as any situation, or location, in which a researcher works in small teams or without a colleague or other person nearby. Researchers collecting data in the in the field, a laboratory, or in the wild, should be cognisant and apply the safeguarding practices that have been developed to protect individuals working in these situations. Researchers collecting data from individuals, need to be aware of risks associated with travel to and from the data collection sites, their presence at the data collection sites, and the known and potential unknown risks arising from interactions with participants. Recommendations on how to address specific risks are available in the Lone Researcher Guidelines.

7.8.2 Risk, harm to site, environment, or society

	Risk to Site, Environment and Society This section is mandatory. Click on the add button below for each site risk. ***Guidance: Risk benefit harm to researcher, environment, and society***. **Add Risk**

All the risks in this instance can be submitted using one submission.

Risk to Site, Environment and Society
Identify the risk from the list below • Risk to environment, site or society • None If none if selected the following additional question will be blocked out and the box is ready to press submission
Estimate the Impact: • Low • Medium • High
Estimate the Probability/ likelihood: • Low • Medium • High
Detail the Mitigation measures *(Text field)*

7.8.3 Risk to participant

Do any of the research team have a dependant relationship to the researcher?	This section is mandatory. Click on the add button below for each researcher risk. *Guidance: Dependant relationship* *Guidance: Participant risk* *Guidance: Revealing information* **Add Risk**

Enter each risk separately by submitting the first risk and selecting the add button again to add more, if applicable.

Add Risk
Identify the risk from the list below • Inconvenience • Physical risks • Emotional risks, including stress or discomfort • Reputational risks • Financial risks including exposure or loss • Loss of privacy • Is the topic potentially intrusive? • The research may be harmful or may potentially endanger the participants • Other • None If other elaborate If none if selected the following additional question will be blocked out and the box is ready to press submission.
Estimate the Impact: • Low • Medium • High
Estimate the Probability/ likelihood: • Low • Medium • High
Detail the Mitigation measures *(Text field)*

7.8.4 Participant benefits and confidentiality

Is it foreseeable that participants could reveal information that you have a legal obligation to disclose (e.g., child protection policy, malpractice, etc.)? Yes/No If answer is yes, what information may be disclosed, why and to whom.	*Guidance benefits*
Outline any direct benefits of participation to research participants	

Guidance: Dependant relationship:

Guidance: participant risk

All projects have some risk and impose some burden upon participants. In assessing the potential risk to participants, consider the worst-case scenario. If your previous experience is not sufficient to gauge the risks that may arise, consult with your supervisory team / colleagues, or with recognised experts in the field. All risks must be specifically identified and stated. On balance the benefit of taking part in a project (which may not be derived directly by the participant) should always outweigh the risks. In most studies inconvenience (i.e., the time it takes to be part of the study), and loss of privacy (i.e., that participants reveal some personal data to the researchers), are the most common risks. These may have relatively low impact, but still need to be minimised. Other projects, particularly intervention studies, may have higher impact, which will requires mitigations. Consider if any other common categories of risk apply (note this is not an exclusive list): Physical risks, Emotional Risks, including stress, distress, or discomfort, reputational risks, financial risks, including exposure or loss, the topic explored is potentially intrusive, the research may be harmful, or it may potentially endanger the participants. Mitigation strategies use various methods. For example, debriefing is a common strategy used in projects that deal with intrusive topics, or that could otherwise cause stress or anxiety.

The risks you cite here, and the mitigations proposed will be imported into the PIL template, in order that they may be brought to the attention of the participants.

Guidance: revealing information

There are certain circumstances in which the researcher is legally obliged to disclose the information revealed by a participant to other parties. This may relate to issues surrounding physical, emotional, and/or sexual abuse, concerns for child protection, rape, self-harm, suicidal intent, criminal activity and malpractice/negligence in healthcare settings.

If there is a **possibility** of such disclosure the statutory limits upon confidentiality must be explained fully in the Participant Information Leaflet and details of the intended actions and pathway of disclosure included (e.g., disclosure of child abuse will be reported to the Gardai).

Guidance Benefits

In some projects participation may be of potential benefit to the participants. In others it has no direct benefits. If there is no **direct** benefit confine your description here to one line such as: There is no direct benefit of participation for the participant, they may become more aware of the topic under study, and this may indirectly benefit them by increasing their knowledge and awareness and their participation will assist in the development of this area to benefit others in the future.

7.8.5 Conflict of interest

Are you aware of any conflict of interest from the PI or any collaborator, processor, or other person involved in the conduct of the project, that could arise in the course of the project? Yes/No If yes: Give details of the Conflict of Interest and what mitigation measures are in place	**Conflicts of Interest** Conflicts of Interest arising from project funding will be dealt with separately and should not be entered here. *Guidance: Conflict of interest*

Guidance: conflict of interest

There are several types of conflict of interest. A conflict of interest may occur when the researcher, their family, or close associates, gains directly and materially from the research, in a manner that goes beyond the benefits that accrue from the advancement in knowledge arising from the research. The gain may be monetary or non-monetary. In addition, a conflict of interest can occur if there are personal interests on the part of the researcher, or other related parties, that could significantly affect the design, methods, or results of the research, or the publication of findings. In line with college policy, interests that could present a real or perceived conflict of interest, should be declared and managed appropriately (Policy for Good Research Practice) (Integrity module).

7.9 Funding

Insert RPAMS number if applicable and available	**Funding** This section is required because you have indicated that your project is funded. *Guidance RPAMS Number and Sources of funding* *Guidance: Conflict of interest arising from funding*
Outline sources of funding, list names of all confirmed sources of funding or support (including in-kind benefit), for each state if it is industrial/commercial, state/public, philanthropic/charitable, other. *(Text field)*	
Please specify any funder specific requirements or obligations which should be brought to the attention of the ethics committee and or Trinity Research & Innovation *(Text field)*	
Will the results of the project be used or disclosed for commercial purposes? Yes/No	
Follow up question if answer is yes: Please clarify which party shall have the commercialisation and/or intellectual property rights. *(Text field)*	
Conflict of interest	
Are you aware of any possible conflict of interest arising from the funding or commercialisation of this project? Yes/No If yes: Give details of the Conflict of Interest and what mitigation measures are in place	
It there likely to be possible conflict of interest between the funders of the project and the aims and results of the project. Yes/No If yes: Give details of the Conflict of Interest and what mitigation measures are in place. *(Text field)*	

Guidance: RPAMS no. and sources of funding

Please include all sources of funding pertaining to this project that you have secured and all those that are pending. Include all types of financial support, charitable, formal, philanthropic, government based etc. If there are multiple sources, please detail the purpose of each i.e., Trinity College 1592 student scholarship: payment of student stipend and college fees. Please note that if you acquire further funding following ethical approval, you must inform the relevant ethics committee by submitting an Amendment.

If you have funding administered by Trinity Research & Innovation (TR&I) you may already have a RPAMS number to insert here. In some cases, you may not yet have an RPAMS number because your contract is not finished or because your project may not have the kind of funding that goes through TR&I.

7.10 Human Biological Samples

This section will be included if the applicant indicated yes to Human biological sample question.

Will the samples in any form be stored for any period after the project completion? Yes/No. If yes, the next three questions will be generated	***Biological Samples*** *Guidance: Biological Samples*
State what type of samples will be stored *(Text Field)*	
Where they will be stored (name specific location, ownership etc.) *(Text Field)*	
Planned date of destruction of sample (Text Field)	
Does the project involve the use of genetic data? Yes/No	

Guidance: biological samples

Careful consideration and respect are required in the gathering, storage, and destruction of biological samples of all types, whether these are small quantities of hair or complete organs. In addition, many biological samples are intrinsically non-anonymous. Considerable care must therefore be taken in managing such samples, and in processing of any records of such samples. In non-longitudinal studies, particularly when data are anonymous, it is best practice that biological samples are destroyed as soon as is feasible, in line with the data retention policy for research records of this nature.

7.11 Data protection

Please note that this section is quite complex particularly if you are not familiar with completing ethics applications at all or recently, please review carefully the linked guidance as you make your way through the questions. Guidance for this section is available from the Data Protection Office linked below:

7.11.1 Opening questions

7.11.2 Data Protection Assessment

7.11.3 Data Protection Risk Assessment (DPRA)

7.11.4 Data Protection Impact Assessment (DPIA)

7.11.5 Data Protection Processing Risks

7.12 Declarations

7.12.1 Applicant's declaration

I declare that the details provided reflect accurately my research plans, that I undertake to carry out these plans as described, will seek further approval if substantive changes are proposed after this submission, report any adverse events or serious complaints, return all required reports, and save and process the project data in accordance with Trinity policies and regulations e.g., data protection, data retention, IP etc.

> **HELP TEXT:** Applicants should be aware that in many cases (e.g., funded research projects), the data collected by staff (in particular) belong to Trinity. The PI of the project is responsible for the development and implementation of the project data plan, for ensuring that the data are processed and retained in line with college policy, and in accordance with the information given in this application. Applicants should contact their school with regards to specific storage policies. Further guidance with respect to recommended practice in relation to storage is provided in the Policy on Good Research Practice, Policy on Good Research Practice, Data protection documentation, Data storage and sharing, Data Management policy and a Data Retention Schedule
>
> *Guidance: Data retention:*

7.12.2 PI declaration

I declare that the details provided reflect accurately my research plans, that I undertake to carry out these plans as described, will seek further approval if substantive changes are proposed after this submission, report any adverse events or serious complaints, return all required reports requested and save and process the project data in accordance with Trinity policies and regulations e.g., data protection, data retention, IP etc.).

> **HELP TEXT:** Applicants should be aware that in many cases (e.g., funded research projects), the data collected by staff (in particular) belong to Trinity. The PI of the project is responsible for the development and implementation of the project data plan, for ensuring that the data are processed and retained in line with college policy, and in accordance with the information given in this application. Applicants should contact their school with regards to specific storage policies. Further guidance with respect to recommended practice in relation to storage is provided in the Policy on Good Research Practice, Policy on Good Research Practice, Data protection documentation, Data storage and sharing, Data Management policy and a Data Retention Schedule
>
> *Guidance: Data retention:*

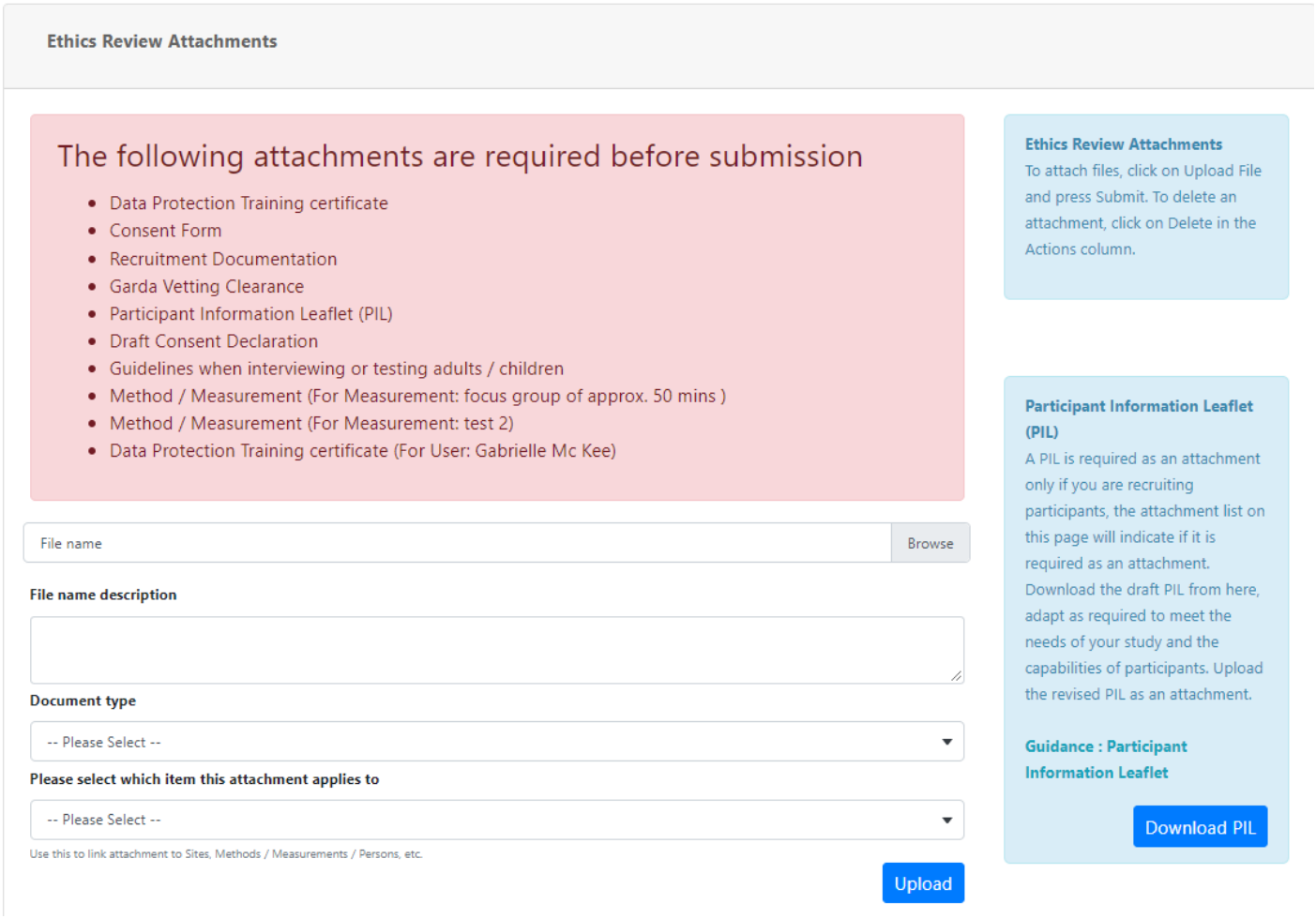
7.12.3 Supervisor declaration

I have read this application. I am satisfied that it is in line with the required college and school ethical criteria and other relevant college policies (e.g., data protection, data retention, IP etc.).

> **HELP TEXT**: I as supervisor will ensure that any required controls with respect to data protection are put in place, and I acknowledge the nature of any risks arising from the processing of data.
> I undertake to ensure that the student provides the required reports, and will support them in the relevant storage and destruction of the project data as planned in line with the Policy on Good Research Practice, Policy on Good Research Practice, Data protection documentation, Data storage and sharing, Data Management policy and a Data Retention Schedule
>
> *Guidance: Data retention:*

7.13 Attachments

As you work your way through the application form, and as indicated earlier, the answers given to certain questions will determine whether specific attachments are required. An attachment list will be generated accordingly. It is necessary that all the attachments included in this list are uploaded before submission can occur.



This above screen save is an example of a project that has a lot of attachments.

For each attachment there is a need to complete four questions cited below the list

1) **File name**: this will allow you to browse in your files and select the file you want to upload.
2) **File name description:** the name you want to give the file i.e., Data Integrity Sean
3) **Document type:** This will give a list of all the types of documents that could be uploaded in alphabetical order, select the one that reflects the document you have just selected to upload i.e. Research Integrity Module Certification.
4) **Please select which item this attachment applies to:** many attachments are affiliated to a specific person or item, scroll through the selection given and select the name/ item that is appropriate in each in this case it would be the Sean's name as it is his certification that was to be uploaded. If you were uploading one of the selected methods/measurement the names blood sample, interview schedule and questionnaire background would be on the list for you to select the one which related to the upload.

When the above steps are complete you can press the upload button and that attachment will be removed from the list. Continue with the same procedure until all the documents are uploaded.

7.14 Participant information leaflet

A Participant Information Leaflet (PIL) is required as an attachment **only** if you are recruiting participants. When you click on the attachment page you will see in the left hand column a tab – download PIL (see screen shot in attachment section). By clicking on this tab, you will generate a draft PIL for your study. This will include a template of the usual information expected in a PIL as well as information exported from your study in a draft format. Adapt the template information according to the characteristics of your study e.g., if the study is not funded or contains no personal data, go to these sections and add a simple line that this study is not funded, or no personal data is collected in this study etc. and delete other information there. Examine carefully the exported information. While it does assist you using the same detail as you have already inserted in the form, it may need significant adaptation, most likely in the following areas: adapt suitable to abilities of the participant, format to be consistent with the rest of the form, deletion and adaption of detail exported. The following guidance will give you further information on this, do be cautious not to delete areas that are required irrespective of the abilities of the participants.

This section starts with generic information and then addresses specific information on each of the potential sections within the PIL.

Generic guidelines on Participant Information Leaflet presentation

The format, style and language of a PIL are equally important areas to address in the content in order to increase accessibility and understanding.

The following are the main principals.

- The **content** of the leaflet particularly the importance of using plain English.
- The **appearance** of the leaflet particularly the font and font size used.
- The National Adult Literacy Agency have provided useful advice on how to ensure the leaflet is suitable for your target audience and is available at www.simplyput.ie.
- For further information consult other projects in your research area.
- A recent clinical reference on this area, drawing from clinical research but with style recommendations suitable for any PIL is Coleman et al., (2021) Preparing accessible and understandable clinical research participant information leaflets and consent forms: a set of guidelines from an expert consensus conference. *Res Involv Engagem*. May;7(1) 31. doi:10.1186/s40900-021-00265-2.

It is important that you get the balance between what is needed and not having too long a PIL. From an ethical and ethics review point it is essential that the contents of the Participant Information Leaflet **match** the details provided in the Application Form. In addition, some items about disclosures and personal data are required legally and **must** be inserted.

Before you start, have a quick look at the entire PIL so you get a good idea where the details are required and best placed, this will save you duplicating information. All information is editable, and much of the exported data will need editing for the layperson and for the context. But take care in what you delete, some information you have to include is your project has personal data or if your project requires explicit consent. Please not if you change exported information here it will not be changed in the core application form so if significantly different than what you said previously in the form you need to correct it there also. Below is a template of what you PIL will look like. Guidance and exported information from your form will be in red, for formatting and adaption appropriate for your participants. Additional guidance in this document is in black in inserted paragraphs, in smaller font.

Participant Information Leaflet

Project Name *(your project name will be inserted here)*

Introductory Statement

Inserted here will be title of your project from your application form. This can be adapted to meet the needs and abilities of your participants. It is recommended that there is consistency between both in meaning and method. Any changes implemented here will not be exported back to the application form, so if you make substantive changes, also insert these into the title box in the application form on the project details page. It is essential all projects that involve students to state that the research is contributing to their studies i.e., their PhD, undergraduate, or master's theses.

You must provide an introductory statement, Consider the following and adapt.

You are invited to take part in a research study that is being done by (*your name will be inserted here*) of (*your affiliation will be inserted here i.e., Trinity college Dublin)*.

Insert another line if you are not the PI and mention your role in the project e.g., PhD student, project manager etc.)

Before you decide, you need to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully. Talk to others about the study if you wish.

At the end of this information leaflet there are my contact details, please ask us, or contact me if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

This leaflet has five main parts:

Part 1 – The Study

Part 2 – Data Protection

Part 3 – Costs, Funding and Approval

Part 4 – Future Research

Part 5 – Further Information

1. **The Study**

Why is this study being done?

Adapt the information below as appropriate. In final draft delete this text

-State research aim(s) and objective(s), research question or hypothesis: *(your data will be inserted here)*

-Lay Summary: including rationale/ justification, research approach, study design (exclude detail of measurement instruments and intervention and analysis (if applicable): *(your data will be inserted here)*

Study Site/s:

Insert study sites/s, adapt the information below as appropriate, in final draft delete this text

All study sites you have cited will be inserted here.

Principal Investigator(s) (PI) and Collaborator(s):

-Applicant name: email, *(your data will be inserted here)*

-Primary employer (if not Trinity) *(your data will be inserted here)*

Trinity Collaborators

A table like below with be inserted, use this information to list and describe your Trinity collaborators and then delete the box.

Name	Email Address	Role	Primary & relevant affiliation	Title (within that organisation)
Anna Ashton	annaash@tcd.ie	Stakeholder: Academic / Clinical / Professional / Industrial Collaborator	School of xxxx	Assistant professor
Ben Button	bbutton@tcd.ie	Stakeholder: Academic / Clinical / Professional / Industrial Collaborator	School of xxx	Assistant professor
Sam Cooke	sxcooke@tcd.ie	Stakeholder: Academic / Clinical / Professional / Industrial Collaborator	School of xxx	Associate Professor

Non Trinity collaborators

A similar table as above with be inserted, use this information to list and describe your non Trinity collaborators and then delete the box.

Why have I been invited to take part?

Adapt the information below as appropriate. In final draft delete this text.

Your list of inclusion/ exclusion criteria will be inserted here. Adapt the above inserts to explain specifically why that person has been invited e.g., because they are a second year student, because there are a certain age group and or have a specific condition.

Do I have to take part?

Develop appropriate detail suitable for the above participants. In final draft delete this text.

Emphasise to participants that participation is voluntary

SAMPLE TEXT: Example (**for studies based in clinical care setting**): You don't have to take part in this study. It is entirely voluntary. If you decide not to take part it won't affect your current or future medical care. You can change your mind about taking part in the study and opt out at any time even if the study has started. If you decide to opt out, it won't affect your current or future medical care. You don't have to give a reason for not taking part or for opting out. If you wish to opt out, please contact [**insert name, role and contact details**] who will be able to organise this for you.

What if I change my mind?

Adapt the information below as appropriate. In final draft delete this text.

Your data will be inserted here.

Explain that participation is voluntary. In this section describe how they can cease their participation in the study, request for their project data to be withdrawn i.e. their questionnaire, interview test or data extracted from a database, and in the data protection section, if applicable, you will describe how their personal data, including biological samples, can be withdrawn.

Describe the process of withdrawal, i.e., contact XXX on 01-XXXXXX, and if applicable and the effect of any such withdrawal.

Depending on the study type and stage the withdrawal of the project data should be facilitated if possible or if the project has not progressed to such a stage that it would virtually prevent the project from being completed.

SAMPLE TEXT

Your personal data can be withdrawn at any time (see below)

This study is an anonymous survey therefore we cannot identity your survey to withdraw it.

Your interview will be merged with all other interviews in approximately two months' time. Following this time, it will not be feasible to withdraw your responses.

The merging and analysis of all returned questionnaires will occur in Jan 2023, following this time it will not be feasible to withdraw your responses.

You can change your mind at any time by contacting xxx [INSERT CONTACT DETAILS usually of the project doctor]. If you choose not to continue to take part, this will not affect your medical care in any way. If you choose not to take part anymore, you will be asked to fill in a withdrawal form. If you wish, you can ask for your samples and/or data stored to be destroyed. If you request this, we will destroy all samples and data that are still in our possession. We will no longer use or share your samples or data for research from this point onwards. However, it will not be possible to destroy samples and data already used in research studies prior to this time (drafted as per a clinical study, adapt according to study)

What will happen if I take part?

Adapt the information below as appropriate. In final draft delete this text.

- Describe the time commitment of participant: *(Your data will be inserted here).*

- What is the proposed sample size -how many participants are involved in the study? *(Your data will be inserted here).*

- What setting/s will be used for data collection? *(Your data will be inserted here).*

- Outline the interventions? *(Your data will be inserted here).*

-Please give a detailed step by step description of how participants will be recruited and append the recruitment material? *(Your data will be inserted here).*

This section will differ greatly from project to project the above exported data will assist to address some of the information needed. Participants need to know exactly what they are consenting to. Keep the language simple. This section needs to detail what will be involved in your research study from a participant's point of view, and in the order they will experience it.

- When and where the project will take place. Where will the participant have to go? How long the participant will be involved in the research, how often they will need to attend a research session and how long visits will be.
- Detail what will happen to the participant e.g., interview, filling out a questionnaire procedures and tests/procedures that will be performed, and by whom and any data of theirs you will use from other sources.
- If research is taking place in the context of clinical care, make clear which parts are research and which standard care.
- A table or flow chart can provide clarity when describing a complex series of interventions.
- Any procedures/tests/ interventions which are experimental should be identified and whether the participants will be randomly allocated to them or not and alternative procedures, programmes or courses of treatment disclosed.

For health projects consider:

- Where involvement in the research involves a change to the 'usual care' this individual would receive, this should be specified.
- If you will be allocating participants randomly to study medication(s) and/or placebo, describe what it means in lay terms.
- Are any of the tests invasive?
- If you will be collecting samples, give an idea of amounts. Blood volume may be more meaningfully expressed in

tablespoons: 5ml is equivalent to 1 teaspoon, 15ml is 1 tablespoon. Biopsies may be compared to grains of rice.

- If you will be using tissue samples, state whether the tissue will already be collected as part of clinical care. Are you requesting use of tissue surplus to diagnostic need, or collecting additional samples?
- Outline any plans for long-term monitoring/follow-up.
- If the study involves the use of any ionising radiation (e.g., x-rays) or non-ionising radiation, such as MRI scans.

Another important item to address in this section is how the **results of the research** will be disseminated e.g., journals, conferences.

SAMPLE TEXT: The results of the study will be reported in medical/scientific journals and disclosed at medical/scientific conferences. No information which reveals your identity will be disclosed.

What will happen to my Samples?

Adapt the information below as appropriate. In final draft delete this text

- Does the project involve: Human biological samples of any size or type that could have impact on future treatment (e.g., human DNA sequencing) *(Your data will be inserted here)*

- Will the samples in any form be stored for any period after the project completion: *(Your data will be inserted here)*

- State what type of samples will be stored: *(Your data will be inserted here)*

- Where they will be stored (name specific location, ownership etc.): *(Your data will be inserted here)*

- Planned date of destruction of sample: *(Your data will be inserted here)*

- Does the PROJECT involve the use of genetic data: *(Your data will be inserted here)*

If this section does not apply to your study delete, if you are collecting biological samples please note these are personal data and you need to process them accordingly, therefore this detail is important to the project and for the participant.

- State how the samples will be used in the research (where they will be transferred or held, what analysis will take place) and in what form (anonymous, identifiable, pseudonymised (coded)).
- Include information on sharing of samples, including details of partner institutes, hospitals, universities and commercial partners.
- If your study involves the analysis or use of DNA, limits on anonymity should be made clear to participants.

SAMPLE TEXT: Your DNA and blood sample will be assigned a code and your data will also be identified only by this number. The material given to researchers will not have information that identifies you. However, your DNA is unique to you so it can never be completely anonymous.

- You should also give potential participants information on your plans for any samples remaining after your specific piece of research has ended, such as whether they will be destroyed or stored, with consent, for future use.

- If samples are intended to be retained for future use, it is worth 'future proofing' by indicating that this research may happen outside of the EEA (and potentially outside of the scope of GDPR). Consider whether the samples may be used by commercial companies.

SAMPLE TEXT: Your pseudo anonymised/anonymised samples will be used mainly by local researchers (if applicable), but ethically approved research projects may also take place in hospitals, universities, non-profit institutions or commercial laboratories worldwide.

- It will also be necessary to retain the Consent Form (personal data) until the sample has been depleted or destroyed in order to provide evidence of consent in accordance with Article 7 GDPR requirements. Please add a statement in the PIL.

SAMPLE TEXT: Biobanks - If you agree to your samples being used in future research, your consent form will be held until the samples have been used up.

Are there any benefits to taking part in this research?

Adapt the information below as appropriate. In final draft delete this text.

Adapt the exported information to provide information on potential benefits if any, to the participant or others, through taking part. If there is no direct benefit to the participant, then this should be stated with only a brief outline of the benefits to others if you feel it is necessary.

SAMPLE TEXT:

Taking part in this study will not directly benefit you. However, research with the information you have provided aims to help us to better understand [INSERT RESEARCH AREA] and may result in new ways of doing things. This is a long-term research project, so the benefits of the research may not be seen for several years. By participating, you are helping to knowledge and practice for future generations.

Are there any risks to me or others if I take part?

Adapt the information below as appropriate. In final draft delete this text

A table of the risks to the participants will be generated from your answers and inserted here

Risk Type	Estimate the impact	Estimate the probability/ likelihood	Detail the mitigation measures
i.e., Loss of privacy	Low	Low	Personal details are collected which always poses a risk. To mitigate against this risk these will be stored …….
i.e., Emotional Risks, including stress, distress, or discomfort	Low	Low	If a participant gets upset in the focus group the focus group will be stopped, ……..

- Is it foreseeable that participants could reveal information that you have a legal obligation to disclose (e.g., child protection policy, malpractice, etc.,) *(Your data will be inserted here).*
- What information will be disclosed, why, and to whom *(Your data will be inserted here).*

This paragraph **always applies**. Provide a fair and honest evaluation of the possible consequences of involvement in the research including key research procedures, this is an essential requirement. This section should include details of appropriate supports for the participants within and outside the study depending on the project this might include general Websites for the area, government agencies, employer support (see next question also).

If it is foreseeable that you legally reveal information you must state this to the participants here and detail including detail of the pathway and the persons you will report the information to i.e., police, line manager.

What happens if something goes wrong with the study?

If applicable, develop appropriate detail for participant above. If this question is not applicable delete. In final draft delete this text

This section may not apply to your study.

- If your study involves a risk and you have measures in place if the risk does materialise, let the participant know e.g., counselling in case of psychological distress, genetic counselling in case of certain genetic results, referral to a **named** specialist or **named** counselling service if something clinically relevant is discovered etc.
- If your study is sponsored by a company, and they have signed an indemnity agreement, let the participant know.

Clinical Health projects: Check as to what procedure is in place in case of withdrawal:

- Are there any safety implications? Will participant involvement be followed up and a final visit arranged?
- Will samples and data collected to point of withdrawal be retained for the study, removed, or will the participant have a choice?
- If the study intends to bank tissue or data for future research, specify the effect of withdrawal on future use.
- Make it clear that it may not be possible to destroy samples and data already used in research studies prior to withdrawal of consent.
- Make it clear to participants if their data will continue to be processed for reasons other than health research (i.e., to provide critical care) if they withdraw consent to their data being processed for health research purposes. Where such data processing will occur the legal basis for such processing should be set out.

SAMPLE TEXT:

In the unlikely event that you are harmed in any way, the researchers on this study are covered by insurance through [INSERT DETAIL]. This insurance will cover you if you are injured as a result of taking part in this study.

What other interventions/ treatments are available to me

If applicable, adapt question to reflect study and develop appropriate detail for participant above. If this question is not applicable delete. In final draft delete this text.

Will I be told about the outcomes of the study?

If applicable, develop appropriate detail for participant. If this question is not applicable delete. In final draft delete this text.

Will I be told the results of any tests or investigations performed as part of this study that relate to me?

If applicable, develop appropriate detail for participant. If this question is not applicable delete. In final draft delete this text.

This question is required in several types of health research, delete this question is not applicable

- Provide clarification whether:
  - Any outcome from the research that would **impact directly or indirectly on the participant's health** will be reported to him/her.
  - The **results of the research** will be reported to the participant.

2. Data Protection

What information about me (personal data) will be used for this research?

If personal data is being collected adapt the information for participant. In final draft delete this text

Your data will be inserted here. No inserts will occur if you are not collecting personal data.

SAMPLE TEXT: This project does not involve the collection personal details about you, data you gave is anonymous and not subject to data protection legal requirements.

If you are not collecting personal data delete the rest of this section.

If there are any inserts this indicates that you are collecting personal data from your participants either as part of your project administration or consent forms etc or within your project data. Therefore, you **must complete** and in this question and its sub-questions.

Review the sub questions in the question first to assist in knowing where all the information relative to this area is best placed.

Provide a description of the **personal data** to be collected and used. List each item you intend to record. Why **identifiable data** rather than anonymised data is required. See next question regarding data that you will extract for database records particularly Health records.

State how the data will be used in the research (where they will be transferred or held, what analysis will take place) and in what form (anonymous, identifiable, pseudonymised (coded)).

Will my personal records be accessed?

If applicable, develop appropriate detail for participant above to indicate if human resource records, medical records, educational records etc. will be used. If this question is not applicable delete. In final draft delete this text.

Who will access and use my personal data as part of this study?

If applicable, develop appropriate detail for participant above. If this question is not applicable delete. In final draft delete this text.

- Is the personal data shared outside the research team with any other units within Trinity College; Provide names of these organisations and detail what personal data will be shared with them and why: *(Your data will be inserted here).*

- If yes outline how you will store the information, keep it confidential, and destroy it in line with the data retention policy: *(Your data will be inserted here).*

- Who is authorised to access the data and describe how this access is controlled: the confidential information in the research data will be accessed by the RA recruiting the data to the rest of the team will be in pseudo anonymous format the PI will have the codes linking. *(Your data will be inserted here).*

- Detail how and when you will code / pseudonymise personal data you are using for the project (if applicable). Detail how the personal data will be archived / anonymised / deleted / destroyed (as applicable): *(Your data will be inserted here)*

Used the exported data to include information on sharing and data, including details of partner hospitals, universities and commercial partners

Will there be any automated decision making and / or profiling?

If applicable, develop appropriate detail for participant above. If this question is not applicable delete. In final draft delete this text

- Could the project result in automated decisions being made, including profiling, or actions being taken against individual(s) in ways that could have a significant impact on them: *(Your data will be inserted here)*

- Does the project involve the evaluation or scoring, including profiling and predicting, of participants to make generalisations about an individual that could lead to significant decisions being made that could directly affect the individual: *(Your data will be inserted here)*

How will my personal data be kept confidential and secure?

If applicable, develop appropriate detail for participant above. If this question is not applicable delete. In final draft delete this text.

- If yes outline how you will store the information, keep it confidential, and destroy it in line with the data retention policy: *(Your data will be inserted here)*

Your data here will be from early in the application form, where you discussed **administration data** that contains personal data including names, addresses, email etc, and consent forms. In the next question you will be addressing how you process etc. any personal data you have in your research data. Note that the processing timing etc. can be different for different types of data, reflecting the need for the data, the project characteristics and the need to minimise the period of data retention of personal data.

- Provide a general description of the security measures in place to keep project data secure for each system, platform and application you will use for access, storage, and transfer, including but not limited to multi factor authentication, use of passwords, use of VPN, device encryption, vendor ISO certification, anti-virus used, use of secure file transfers such as HEA net, and detail on how data is backed up etc.: *(Your data will be inserted here)*.

- Detail how long personal data will be retained for in an identifiable or coded format: *(Your data will be inserted here)*

The information exported here will be about your **research data**, as above address the questions using this information that you have cited about your research data. Include details of other data controllers, data processors, third parties that will have access to the personal data.

- Information on how the data will be kept secure should be provided, and who is responsible for ensuring data security. This should include details of restricted access to the data, use of software encryption, firewalls etc.
- Confirm that arrangements are in place so that personal data will be processed only as is necessary to achieve the objective of the research and will not be processed in a way that damage or distress will be caused to the participant.
- State the length of time the personal data will be kept (in an identifiable or pseudonymised format) and why it is necessary to keep it for that period.
- State the arrangements to be made for the personal data to be archived or destroyed.
- State whether the personal data collected will leave the State and if so what countries it will go to and why it is going to those countries.
- If applicable, state the existence of automated decision-making, including profiling and information about the logic involved, as well as the significance and the envisaged consequences of such processing for the data subject.

Will my personal data be kept confidential? How will my data be kept safe?

Outline the confidentiality and security measures in relation to the participant's data.

- Describe the data security arrangements in place.
- Confirm that a Risk Assessment of the data protection implications of the health research and /or a Data Protection Impact Assessment was carried out and an indication of the level of risk identified by either or both.
- State whether any presentation or publication in relation to the study could identify the participant.

- Confirm that the persons carrying out the research or otherwise having access to the personal data are bound by a professional code of secrecy (like doctors) or a contractual code of secrecy (that would mean disciplinary action for employees who disclosed or facilitated unauthorised access to the personal data) or some other arrangement that emphasises confidentiality (this may be applicable in the case of medical students).
- Confirm that training in data protection law and practice has been provided to those individuals involved in carrying out the research.

SAMPLE TEXT: Your privacy is important to us. We take many steps to make sure that we protect your confidentiality and keep your data safe. Here are some examples of how we do this:

However, if something did go wrong we …..

What is the legal (lawful) basis to use my personal data?

Insert the information below as appropriate. In final draft delete this text.

- Indicate which Article 6 lawful basis you are relying on for the use of Personal data. *(Your data will be inserted here)*

- Please list which Article 9 condition(s) you are relying on for the use of Special Category personal data - select all that apply *(Your data will be inserted here).*

What are my rights under data protection law?

Insert the information below in the final draft delete this text.

- Describe plans that are in place for responding to any requests from individuals in relation to their data protection rights. *(Your data will be inserted here)*

Below are participants rights that need to be considered

State the **rights** individuals have regarding their **data**.

- Right to access data held
- Right to restrict the use of the data held
- Right to correct inaccuracies
- Right to have information deleted
- Right to data portability
- Right to object to profiling

SAMPLE TEXT:

You are entitled to:

- The right to access to your data and receive a copy of it
- The right to restrict or object to processing of your data
- The right to object to any further processing of the information we hold about you (except where it is de-identified)
- The right to have inaccurate information about you corrected or deleted
- The right to receive your data in a portable format and to have it transferred to another data controller
- The right to request deletion of your data

By law you can exercise the following rights in relation to your personal data, unless the request would make it impossible or very difficult to conduct the research. You can exercise these rights by contacting your study contact person [INSERT NAME

AND CONTACT DETAILS] or the Trinity College Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: www.tcd.ie/privacy.

Data Protection Officer

Data Protection Officer
Secretary's Office
Trinity College Dublin
Dublin 2

Data Protection Officer of site

If applicable enter the name and contact details for the Data Protection Officer of other research and data collection sites. In final draft delete this text.

3. Costs funding and approval

Has this study been approved by a research ethics committee?

Adapt the information below as appropriate, include all relevant sites from which ethical permission have been obtained etc. In final draft delete this text.

Does this site / source require license to use, access permission and /or ethics approval for this site/source	Name source of permission (e.g., of licensor, ethics committee, person who grants permission for each site/source) or explain why permission is not required
i.e., licence	i.e., National Broadcasting Association
i.e., Site/ source ethics required but not yet obtained from this site	i.e., Department of education

The table that has been created with your data has been exported above, use the information it contains to explain to your participants the permission/s and ethics approval/s you have in place, also include the name of the Trinity research ethics committee, the approval number, the date of approval, the number of the application and the contact details of the committee.

Who is sponsoring / funding this study?

If applicable, develop appropriate detail for participant above. If this question is not applicable delete. In final draft delete this text.

- Outline sources of funding, list names of all confirmed sources of funding or support (including in-kind benefit), for all state if they are industry/commercial, state/public, philanthropic/charitable, other: *(Your data will be inserted here)*

- Specify any funder specific requirements or obligations which should be brought to the attention of the ethics committee and or Trinity Research & Innovation: *(Your data will be inserted here)*

Will the results be used for commercial purposes?

If applicable, develop appropriate detail for participant above. If this question is not applicable delete. In final draft delete this text.

- Will the results of the project be used or disclosed for commercial purposes: *(Your data will be inserted here)*

- Are you aware of any possible conflict of interest arising from the funding or commercialisation of this project: *(Your data will be inserted here)*

Indicate that the participant will not commercially benefit from the study if applicable.

Is there any payment for taking part? Will it cost me anything if I agree to take part?

If applicable, develop appropriate detail for participant above. If this question is not applicable delete. In final draft delete this text

- Will payment be made to research participants: *(Your data will be inserted here)*

- Provide further information: *(Your data will be inserted here)*

Adapt the information above to clearly indicate, if any payments or reimbursements for expenses will be provided.

SAMPLE TEXT: No, we are not paying patients to take part in the study. However, you will be reimbursed for travel expenses.

4. Future Research

Indicate clearly to the participant that they are consenting only to the **current study** described in this participant information leaflet.

If this is not so describe in lay terms the intended future uses of the research participants' data/biological material.

- Explain if this will be your research or it could be someone else's research.
- Make it clear this participation is voluntary and they can withdraw their consent to future research at any time.
- Make it clear that this research will only take place if it has research ethics approval.

Note: for Health Research, the Health Research Regulations state that for a researcher to conduct health research 'explicit consent has been obtained from the data subject, prior to the commencement of the health research, for the processing of his or her personal data for the purpose of specified health research, either in relation to a particular area or more generally in that area or a related area of health research, or part thereof'.

In relation to the use participant personal data as part of future research studies, the Trinity Research Ethics Committee interprets the Health Research Regulations as allowing researchers to seek participant consent to use his/her personal data for future health research purposes providing that:

- The future health research is, at a minimum, specified to the general area or a health-related area of the original research
- The data processing measures and safeguards in existence for the original study are in place for any future studies (in addition to any future data processing regulations that may be introduced)
- The participants are informed as much as possible when obtaining consent for future use of their personal data.

Although the Health Research Regulations apply to data processing only, the same standards are applied for research intending to use biological data in future studies.

Will my personal data be used in future studies? (May not apply)

Will my biological samples be used in future studies? (May not apply)

5. Further information

Adapt the questions below depending on your study.

Who do I contact for more information?

Insert your contact details if you are the contact person for the participants of the project. For your own protection do not use home addresses or home phone numbers.

This would be the place to insert detail about how participants can get in contact with you if they want to know the results of the study, remember depending on the study you may not have their contact details or you may have already destroyed them.

Who do I contact if I have a concern about how information about me has been used for this study?

Consider the risk of your project and the likelihood of inserting this question and related information. The appropriate person in this case, could be the principal investigator, the data protection officer/s or the relevant manager from the site where the study was conducted.

Will I be contacted again?

State clearly also whether you intend to **contact** the participant following their participation in the study and the circumstances under which this contact will be made e.g., study results, future research.

Thank you for taking the time to read this Participant Information Leaflet

Appendix 1: Routing to Level 2 and level 3 RECs (Research Ethics Committees)

by Faculty and School

Faculty of Arts Humanities and Social Sciences (AHSS)

School	Department	Level 2 REC	Level 3 REC
Business		School of Business	Faculty of AHSS
Creative Arts	Drama and Theatre Studies	School of Creative Arts	Faculty of AHSS
	Film Studies	School of Creative Arts	Faculty of AHSS
	Music	School of Creative Arts	Faculty of AHSS
Education		School of Education	Faculty of AHSS
English		Faculty of Arts, Humanities & Social Sciences	Faculty of AHSS
Histories and Humanities	Centre for Gender and Women's Studies	School of Histories and Humanities	Faculty of AHSS
	Classics	School of Histories and Humanities	Faculty of AHSS
	History of Art	School of Histories and Humanities	Faculty of AHSS
	History	School of Histories and Humanities	Faculty of AHSS
Languages, Literatures and Cultural Studies	Centre for European Studies	School of Languages Literatures and Cultural Studies	Faculty of AHSS
	French	School of Languages Literatures and Cultural Studies	Faculty of AHSS
	Germanic Studies	School of Languages Literatures and Cultural Studies	Faculty of AHSS
	Hispanic Studies	School of Languages Literatures and Cultural Studies	Faculty of AHSS
	Irish and Celtic Languages	School of Languages Literatures and Cultural Studies	Faculty of AHSS
	Italian	School of Languages Literatures and Cultural Studies	Faculty of AHSS
	Russian and Slavonic Studies	School of Languages Literatures and Cultural Studies	Faculty of AHSS

	Near and Middle Eastern Studies	School of Languages Literatures and Cultural Studies	Faculty of AHSS
Law		School of Law	Faculty of AHSS
Linguistic, Speech and Communication Sciences	Centre for Deaf Studies	School of Linguistics, Speech & Communication Sciences	School of Linguistic, Speech & Communication Sciences
	Centre for Language and Communications Studies	School of Linguistic, Speech & Communication Sciences	School of Linguistic, Speech & Communication Sciences
	Clinical Speech and Language Studies	School of Linguistic, Speech & Communication Sciences	School of Linguistic, Speech & Communication Sciences
Psychology		School of Psychology	School of Psychology
Social Sciences and Philosophy	Economics	School of Social Science and Philosophy	Faculty of AHSS
	Philosophy	School of Social Science and Philosophy	Faculty of AHSS
	Political Science	School of Social Science and Philosophy	Faculty of AHSS
	Sociology	School of Social Science and Philosophy	Faculty of AHSS
Social Work and Social Policy		School of Social Work and Social Policy	School of Social Work and Social Policy
School of Religion	Peace Studies	School of Religion	Faculty of AHSS
	Religious Studies	School of Religion	Faculty of AHSS
	Irish School of Ecumenics	School of Religion	Faculty of AHSS
	Loyola Institute	School of Religion	Faculty of AHSS
	Trinity Centre for Biblical Studies	School of Religion	Faculty of AHSS

Faculty of Science, Technology, Engineering and Mathematics (STEM)

School	Department	Level 2 REC	Level 3 REC
Biochemistry and Immunology		Faculty of STEM	Faculty of STEM
Chemistry		School of Chemistry	Faculty of STEM
Computer Science and Statistics	Computer Science	School of Computer Science and Statistics	School of Computer Science and Statistics
	Statistics	School of Computer Science and Statistics	School of Computer Science and Statistics
Engineering	Civil, Structural and Environmental Engineering	School of Engineering	Faculty of STEM
	Electronic and Electrical Engineering	School of Engineering	Faculty of STEM
	Mechanical, Manufacturing and Biomedical Engineering	School of Engineering	Faculty of STEM
Genetics and Microbiology	Genetics	-	Faculty of STEM
	Microbiology	-	Faculty of STEM
Mathematics		Faculty of STEM	Faculty of STEM
Natural Sciences	Trinity Centre for the Environment	School of Natural Sciences	Faculty of STEM
	Botany	School of Natural Sciences	Faculty of STEM
	Geography	School of Natural Sciences	Faculty of STEM
	Geology	School of Natural Sciences	Faculty of STEM
	Zoology	School of Natural Sciences	Faculty of STEM
	Centre for Biodiversity Research	School of Natural Sciences	Faculty of STEM
Physics			Faculty of STEM

School	Department	Level 2 REC	Level 3 REC
Dental Science		School of Dental Science	Faculty of Health Sciences
Medicine	Centre for Global Health	Health Policy & Management / Centre for Global Health	Health Policy & Management / Centre for Global Health
	Centre for Health Policy and Management	Health Policy & Management / Centre for Global Health	Health Policy & Management / Centre for Global Health
	Anatomy	School of Medicine	Faculty of Health Sciences
	Clinical Medicine	School of Medicine	Faculty of Health Sciences
	Clinical Microbiology	School of Medicine	Faculty of Health Sciences
	Haematology	School of Medicine	Faculty of Health Sciences
	Histopathology and Morbid Anatomy	School of Medicine	Faculty of Health Sciences
	Immunology	School of Medicine	Faculty of Health Sciences
	Medical Gerontology	School of Medicine	Faculty of Health Sciences
	Obstetrics and Gynaecology	School of Medicine	Faculty of Health Sciences
	Occupational Therapy	School of Medicine	Faculty of Health Sciences
	Paediatrics	School of Medicine	Faculty of Health Sciences
	Pharmacology and Therapeutics	School of Medicine	Faculty of Health Sciences
	Physiology	School of Medicine	Faculty of Health Sciences
	Physiotherapy	School of Medicine	Faculty of Health Sciences
	Psychiatry	School of Medicine	Faculty of Health Sciences
	Public Health and Primary Care	School of Medicine	Faculty of Health Sciences
	Radiation Therapy	School of Medicine	Faculty of Health Sciences
	Surgery	School of Medicine	Faculty of Health Sciences
	Unit of Nutrition and Dietetic Studies	School of Medicine	Faculty of Health Sciences

Nursing and Midwifery		School of Nursing & Midwifery	Faculty of Health Sciences
Pharmacy and Pharmaceutical Sciences		School of Pharmacy and Pharmaceutical Sciences	Faculty of Health Sciences