

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

Making An Application

(To read alongside making an application)

Trinity College Dublin

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1. Introduction

This document is designed to provide advice 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) that involves wholly clinical research in a hospital setting. Research that involves biological samples taken from patients (even in a hospital setting) but then used in a research setting can make their applications through REAMs. 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 manual 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.

The purpose of this manual 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.

This manual 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. 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 search topics.
2. **Search 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 search documents are located close to the sections of the form to which they apply.

3. **Specific Research Ethics Committees:** The aim of this document is to provide generic advice that is applicable to all users. It may be the case that the REC to which an application is being made, has provided specific advice 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.

1.1 REAMs Application Form

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 pertaining to researcher, participant, site.
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 Information	Required if the Research Data being processed, could directly or indirectly identify a living individual (if there is any processing of personal data even if data is coded)
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 utilises human biological samples

1.2 Screen shot of Help Text

Applicant Details
This section is required for all projects.

Search: Role on Project

Search: Data Protection

Search: Research Integrity

Refer to the following documents:
[Trinity Policy on Good Research Practice](#)
[Research Integrity Training \(PhDs\)](#)
[EPIGEUM Research Integrity Training \(staff\)](#)
[Data Protection Training Module](#)

2. Advice 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.

2.1 Introduction to the REAMS system

2.1.1 Sign in and outline of early pages

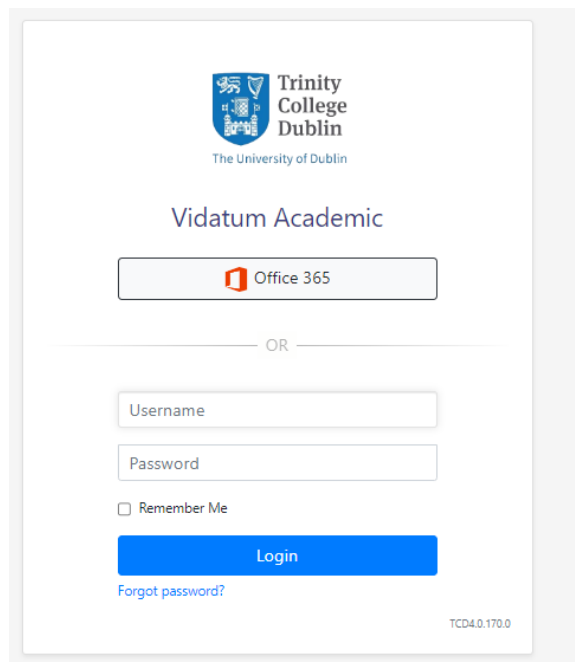
The web address for the online systems is:

<https://ethics.tcd.ie>

You can also access it from the following support website:

<https://www.tcd.ie/research/support/ethics-approval.php>

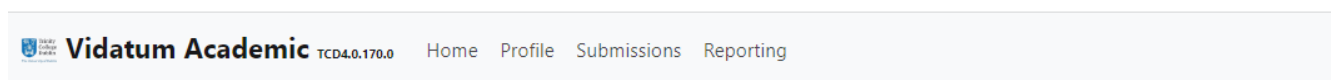
When you open this, the screen below will appear.



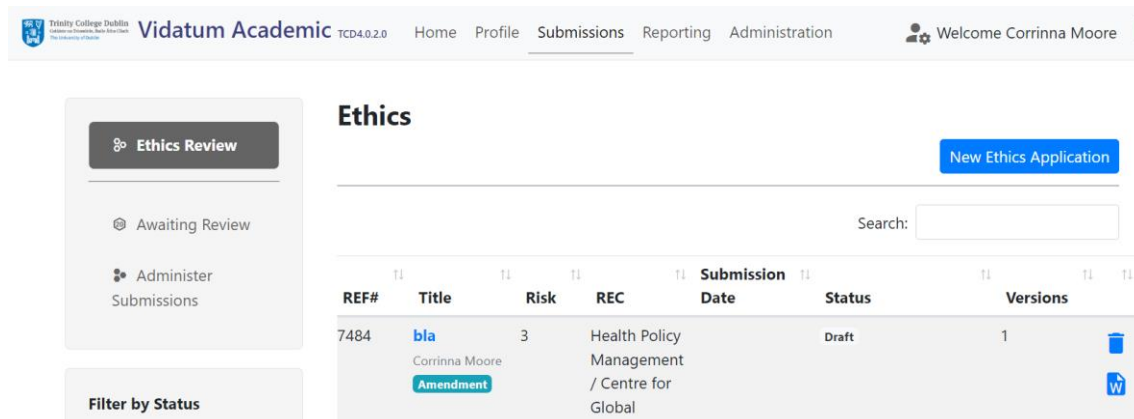
Trinity academic staff and students are automatically registered on the system and log in using the Office 365 button

Non-TCD collaborators (who have pre-registered) may log in using their email address and select forgot password

- The following screen will then appear with your name and college details, any notifications or tasks that you have from previous or current submissions, and a navigation bar along the top (see below):



- Click on the submissions tab and the following will appear:



- Click on the New Ethics Application tab and the following screen will appear with a pop-up screen:
 - This asks you to verify that your research requires ethical approval by consulting a checklist [here](#)

- It also advises you of the data protection review process explained [here](#)

New Ethics Review



Not all research on humans and/or their data or animals requires ethical approval. Check if your research requires ethical approval by referring to this set of criteria [here](#).

Please note that your application may require assessment from the College Data Protection Office. This could result in an extended application process which should be considered from the outset. Please review the information provided [here](#) before commencing your application



I confirm that I have checked the relevant criteria and reviewed the new data protection process

- Once you have confirmed that you have verified these, another pop-up appears and you can enter the project title and select if the application is a new one or an amendment to an existing application

- The next screen shows the opening page of the application and all applications are assigned a risk level 2 to start with.

test **Risk 2**

The risk level may change as you answer the questions in the application form. When you complete and save the project details page the final risk level will be displayed. You should refer to this to ascertain which ethics committee you will be applying to so that as soon as possible you can determine which ethics committee your application will be routed to in order to check further details with them eg. the schedule for the 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 help relating to them for each of these tabs.

Note the save and error buttons. The application form does not automatically save but you can press the save button at any time even if that section /page is not complete. The error button, when clicked, will indicate the section/ pages that

are incomplete. When you revert to any of the pages indicated, the question(s) to which the error applies will be highlighted in red. If the error is still present after you have responded to the question highlighted in red, there remains an outstanding task related to an action button in the side tab.

2.2 Applicant and Collaborators

This is where you give your detail as an applicant and those of any collaborators who may be working on the project with you.

1.1 Applicant Details

1.1.1 Applicant Name * ⓘ	1.1.2 Are you applying as a member of staff or a student? * ⓘ
<input type="text" value="Corrinna Moore"/>	<input type="text" value="-- Please Select --"/>
1.1.3 Staff / Student Number * ⓘ	1.1.4 Email Address * ⓘ
<input type="text" value="22201297"/>	<input type="text" value="Moorec22@tcd.ie"/>
1.1.5 School / Department * ⓘ	1.1.6 Role on the Project * ⓘ

TCD4.0.2.0 Home Profile Submissions Reporting Administration Welcome Corrinna Moor

<input type="text"/>	<input type="text"/>	
1.1.9 Course (for student applicant only) * ⓘ	1.1.10 Part time / full time * ⓘ	
<input type="text" value="-- Please Select --"/>	<input type="text" value="-- Please Select --"/>	
1.1.11 I have read and understood Trinity's policy on good research practice * ⓘ	1.1.12 I have completed a TCD Research Integrity Training Module * ⓘ	1.1.13 I have completed a Data Protection Training module within the last 24 months * ⓘ
<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA	<input type="radio"/> Yes <input type="radio"/> No

2.2.1 Applicant Details

<p>Applicant name</p> <p>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</p>
<p>Is the applicant applying as a member of the staff or as a student?</p>
<p>Staff/ Student number (autofill)</p>
<p>Email address (autofill)</p> <p>Applicants need to use their Trinity email address to apply for ethics approval in Trinity</p>
<p>School / Department (autofill)</p> <p>The answer to this question is one of the characteristics used to route the application to the correct REC.</p> <p>NB 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</p>
<p>Role on the Project (drop down menu select one): Principal Investigator, Non Principal investigator, Other</p> <p>NB. If you are not the PI of the project the PI will also be asked to approve the project before submission.</p>
<p>Primary Employer (if not TCD): (Text field)</p> <p>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.</p>
<p>Other affiliations (If applicable) (Text field)</p> <p>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.</p>
<p>Course (for student applicant only) (autofill): PhD, Master by research, Taught Masters, UG etc</p>
<p>Part time / full time (student only) (autofill)</p>
<p>I have read and understood Trinity Policy on Good Research Practice, Yes/No</p>
<p>I have completed the Integrity module Yes/No/NA (if yes a certificate of proof to attach will be requested a</p> <p>NB. Applicants who are undertaking animal studies may choose NA.</p> <p>NB. Staff and non-PhD students may access the Epigeum Research Integrity Training.</p> <p>NB. PhD students (except staff that are conducting PhDs) <u>must</u> complete the Research Integrity in the Open Scholarship Era Training</p>
<p>I have read and completed an up-to-date Data Protection training module in the last 24 months Yes/No</p> <p>NB. 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.</p>

NB. Helpful links to definitions/ further information

This section is required for all projects. If you are unsure you can click on the links below to get definitions

[Search: Role on Project/PI](#)

[Search: Data Protection Training](#)

[Search: Research Integrity](#)

[Trinity Policy on Good Research Practice](#)

[Data Protection Training Module](#)

[Research Integrity in the Open Scholarship Era Training](#)

Search: Role in Project/PI

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.

Search 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](#).

Search Data Protection Training

If a Project involves the processing of Personal Data, all Trinity members of the research team will be required to successfully complete data protection training every two years - a key requirement under GDPR. Submission of the ethics application will not be possible until evidence of training completion has been provided.

The Trinity [Data Protection Training Module](#) is available online via Blackboard. If you are a member of staff, you will be required to upload your certificate of completion of this module to your ethics application. Certificates can be downloaded from the module web page.

If you are a PhD student, you will be required to complete the Trinity [Research Integrity and Impact in an Open Scholarship Era \(CA7000\) Module](#). A certificate of successful completion should be attached to the ethics application.

If you are an undergraduate or masters student, your designated primary supervisor must provide evidence that they have successfully completed data protection training at the College since May 2021.

Completion of other training modules, such as HSE Land, will be accepted if attached to the ethics application.

2.2.2 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.

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.

Trinity Collaborators

No data available 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. See Guidance Document: Trinity Collaborators

[Add Trinity Collaborators](#)

Project Role (drop down menu select one only)

- Trinity Principal Investigator
- Stakeholder: Academic/ Clinical/Professional/ Industrial Collaborator
- Primary Supervisor
- Trinity Co supervisor/s

NB. Student applications must include a Primary Trinity Supervisor in this section.

Name

Email Address

School or relevant affiliation (Text Field)

NB. 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)

2.2.3 Non-Trinity Collaborators

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

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

Non-Trinity Collaborators

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

[Search: Non-Trinity Collaborators](#)

[Search: Participant Collaborator/ Participatory Research](#)

[Add Non Trinity collaborators](#)

Name
Email Address
Project Role (drop down men select one only) <ul style="list-style-type: none">• Stakeholder: Academic/ Clinical/Professional/ Industrial Collaborator• Public or Participant Collaborator• Non Trinity Co supervisor• Principal investigator (non-Trinity)
Primary or relevant affiliation (<i>Text Field</i>) NB. 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 (within that organisation) (<i>Text Field</i>)
Country (Drop down menu) NB. 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.

NB. Helpful links to definitions/further information

[Search: Trinity Collaborators](#)

[Search: Non Trinity Collaborators](#)

[Search: Participant collaborator and participatory research](#)

Search 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 before submission. Note that, at any time, you can download the application as a word document and forward this and the attachments to external collaborators for review. This section is for Trinity collaborators only. If a Primary supervisor and the PI is one and the same person enter them as the supervisor only, if the PI is a co supervisor enter as PI. 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.

Search: 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 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 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.

Search: Participant Collaborator/Participatory Research

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.

2.3 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, up to 11 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.

2.3.1 Main project details

This subsection appears for all projects including animal projects. This section is required in all projects. Read the manual carefully when completing this section.

NB. 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.

2.1 Main Project Details

2.1.1 Title of Project *

2.1.2 Data Collection Start Date * 2.1.3 Data Collection End Date * 2.1.4 Project end date *

2.1.5 Does the project involve *

2.1.8 Could the research have detrimental legal, economic or social consequences for either the participant or their establishments * Yes No

2.1.9 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 participants Have a military role Have a dual purpose that could be mis-directed to do harm None of the above

2.1.10 State research aim(s) and objective(s), research question or hypothesis (Word limit :100 words) *

2.1.11 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) *

2.1.12 Identify all countries where data is collected or processed *

2.1.13 Does the project involve *

2.1.14 Is the project funded * No Yes

Main Project Details
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 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.

Home Profile Submissions Reporting Administration Welcome Corinna M...

Search: Start Dates
Search: Writing Phase
Search: Deception Research
Search: Potentially Intrusive or Harmful
Search: Dual Purpose
Search: Aims and Objective (s) and Summary
Search: Invasive/ Non-invasive
Search: Research in a Foreign Country
Search: Funding
Search: Aggregate Data
Research Integrity in the Open Scholarship Era Training
Data Protection Training Module

Title of project (*Text field*)

NB. 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

NB. 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.

NB. 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

NB. 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

Could the research have detrimental legal, economic or social consequences for either the participants or their establishments. Yes/ No

NB. 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

NB. 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.

NB. 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)

NB. If you cannot select an answer to this question consult the manual as to what study types require ethics.

NB. Answers 3-5 will facilitate routing to Level 3.

NB. 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

NB. Links to definitions/further information

[Search: Start dates](#)

[Search: Writing Phase](#)

[Search: Deception Research](#)

[Search: Invasive, harmful or may endanger humans](#)

[Search: Dual purpose research that could be misdirected to do harm](#)

[Search: Aims and objective \(s\) and summary](#)

[Search: Research in a foreign country](#)

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

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

[Search: Invasive and non-invasive descriptions.](#)

[Search: Funding](#)

[Search: AREC/ animal research projects](#)

[Search: 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.

Search: 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.

Search 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.

Search: 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.

Search: 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>]

Search: 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.

Search: Aims and Objectives

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

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).

Search: Funding

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.

Search: 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.

Search: AREC Animal Research Projects

1. **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).
2. **Very low risk wildlife and ecology projects:** these projects will be routed to Level 1
 - 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.
- 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.

2.3.2 Details on Human Participants and Their Data

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:

2.2 Details on Human Participants and their Data

2.2.1 Is your study a phased study? *

No
 Yes

2.2.3 Does the project use data from? *

Primary sources only
 Secondary sources only
 Both primary data and secondary sources

2.2.4 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. *

No
 Yes

2.2.6 Will payment be made to research participants? *

YES - standard gratuity with or without expenses
 YES - a higher value gratuity with or without expenses
 No

2.2.8 Is the Project Health Research? *

No
 Yes

2.2.9 Does the project require a Consent Declaration under the Health Research Regulations (2021)? *

Yes
 No

Please note that this is a specific declaration for Health Research and is NOT a consent form

2.2.10 Are you processing any personal data for your research project? *

No
 Yes

Note this question only applies to research data see question below for other project information that has personal information

2.2.11 Are you processing any pseudonymised (coded) data for your research project? *

No
 Yes

Note this question only applies to research data see question below for other project information that has personal information

2.2.12 Are you processing any personal data for participant recruitment? *

No
 Yes

I.e. contact details, consent forms

2.2.13 If yes outline how you will store the information, keep it confidential, and destroy it in line with the data retention policy.

Test

2.2.14 Which of the following best describes the general characteristics of the target population? *

Adults currently not at risk of vulnerability
 Adults at risk of vulnerability
 Participants who require support to give consent
 Children (<18 years)
 Participants with a dependent relationship with the researcher
 Students of Trinity
 Staff of Trinity

2.2.15 Do any of the following further describe the characteristics of the target population? *

participants recruited because of a current or previous medical condition or treatment
 participants recruited because of a current or previous non medical condition or treatment
 Healthy controls/participants, e.g. those used in the control arm of a health trial study
 Other

2.2.17 List the inclusion/ exclusion criteria for selection of project participants *

Test

Details on Human Participants & their Data

There are two types of phased research:

- One involves independent phases ie where one method is independent of the other-one. An application can be submitted if all the methods etc are ready to upload for review.
- The other involves distinct but interdependant phases (eg. phase 1 results in the development of a questionnaire to be used in phase 2). These studies require separate ethics approval for each phase i.e. separate submissions which can then be referenced or linked by the title of the study.

Search: Phased Research

Research data is the data required to meet the aims and objectives of the study.
If primary sources is selected, a Participant Information Leaflet (PIL) will be required.
Search: Participant Information Leaflet (PIL)

TCD4.0.2.0 Home Profile Submissions Reporting Administration Welcome Corrinna Moo

Explicit Consent Template for Health Research

If your research is Health Research you must use the Explicit Consent template unless one of the exceptions for its use are met, see Health Research section.

If paying participants refer to:

Trinity's Gift Voucher Policy
Search: Health Research
Search: Consent Declaration
Search: Personal Data
Search: Directly and Indirectly Identifiable Data
Search: Data Retention
Search: Risk of Vulnerability
Search: Healthy Participants in a Health Trial
Search: Dependant Relationship
Policy on Good Research Practice
Staff and students of Trinity as participants details

Is your study a phased study?

Does the project use data from: *(select one only)*

- Primary sources only
- Both primary sources and secondary sources
- Secondary sources only

NB. 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

NB. 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

NB. 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

NB. 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

Are you processing any personal data for your research project? Yes/No

NB. This question only applies to research data see question below for other project information that has personal information

*NB. Answer yes to processing any personal data and the project **cannot be** routed to Level 1 and a data protection section will be generated*

Are you processing any pseudonymised (coded) data for your research project?

NB. This question only applies to research data see question below for other project information that has personal information.

*NB. Answer yes to processing any personal data and the project **cannot be** routed to Level 1 and a data protection section will be generated*

Are you processing any personal data for participant recruitment? e.g., contacting individuals Yes/ No

NB. 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.

NB. 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

NB. If answer is b-d the project will be routed to Level 3 ethics committees.

NB. If e & f are selected this will add the required permissions as a required attachment.

NB. 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

NB. If other is selected an additional text box will appear:

Please Describe

List the inclusion/ exclusion criteria for selection of project participants (*text field*)

NB. Links to definitions/further information

[Search: Phased Research](#)

[Search: Informed Consent](#)

[Search: Proxy](#)

[Search: Assent](#)

[Search: Explicit Consent](#)

[Link to Explicit Consent templates](#)

[Search: Health Research](#)

If paying participants refer [Gift Voucher Policy](#).

[Search: Processing Personal data](#)

[Search: Data retention](#)

[Search Risk of Vulnerability](#)

[Search: Healthy participants in a Health trial](#)

[Search: Dependant relationship](#)

[Policy on Good Research Practice](#)

[Search: JREC](#)

[Search: Phased Research](#)

There are two types of Phased research:

- One involves independent phases ie where one method is independent of the other: in such cases you can submit one application but must have all your methods ready to upload for review and should add each independent method/measurement separately to distinguish them from one another. Please note that ethical review can only be completed if all phases are presented-no deferrals are permitted.
- The other involves the collection of data using different methods at different times in distinct phases in which the phases are dependant on one another (i.e. phase 1 results in the development of a questionnaire to be used in phase 2): these studies require separate ethics approval for each phase i.e. separate submissions which can then be referenced or linked by the title of the study. Please note that the REAMs platform assumes that ethics approval for phased research will be requested in two separate phases. As a result, the question on phased research has a drop down field that asks the applicant to leave the field blank if it is a first study i.e. only filling it in if it is a second study (sharing the name with the first study for reference)

[Search: JREC](#)

Projects approved by the Joint Research Ethics Committee (James & Tallaght Hospitals) (JREC) involve wholly clinical research in a hospital setting and are not part of REAMs. Research that involves biological samples taken from patients (even in a hospital setting) but then used in a research setting can make their applications through REAMs.

[Search: Informed Consent](#)

This is the process whereby potential research study participants are given information about a project which is sufficient to help them make an informed choice as to whether they wish to participate or not. For consent to be valid there is a two-stage process involved - Transparency of Processing and Demonstrable Consent.

A Participant Information Leaflet is an important document for a number of reasons. It provides potential research participants with the information they need to fully understand what taking part in a research study means for them. It allows them to weigh up the risks and benefits of taking part. It also ensures that the researcher has a record of the information given to the participant at the time when they consented to take part. The Information Leaflet ensures transparency of processing and allows Trinity College Dublin to demonstrate its responsibilities and obligations under data protection legislation as a data controller.

The Information Leaflet should give potential participants easy to read and accessible information in a timely manner, without compromising clarity, to enable them to give their informed consent. It also provides potential participants with information on where to get additional information and support if needed.

After reading the Information Leaflet, potential participants should be encouraged to ask any questions they may have. Additionally, potential participants should be given sufficient time to consider if they wish to participate in the study. Once a participant is happy that all of their questions have been answered, and they have fully understood what the research is about, what their participation in a Project will entail and any risks that may be involved, they can provide their consent.

In studies that recruit human participants, consent must always be recorded.

Best practice is that participants provide their written consent to participate using the study's Consent Form. The form should be signed by the participant and countersigned by the researcher. A copy should be provided to the participant and a separate copy should be retained by the researcher.

These two stages - the information-giving process and the consent-gathering process - make up the informed consent process.

The Information Leaflet and Consent Form together provide written evidence of informed consent. You must keep records of these documents provided to research participants.

In some limited circumstances, such as anonymous surveys, consent may be indicated by ticking a single box. More usually, a more expansive *tick list* is provided.

Trinity College Dublin has developed templates and materials to ensure consistency of practice. For further information please see <https://www.tcd.ie/dataprotection/research/>.

Search: Explicit Consent

If your Project is "health research", as defined in the [Health Research Regulations 2018](#) (as amended), you need to ask participants to consent to take part in the research project and (separately) to consent to the use of information for the specific area of health research or more generally in that area. As the term implies, explicit consent requires an express statement of consent, i.e. an affirmative action and genuine choice as to what to consent to (e.g. permission to use personal data for future research or sharing with industry). Detailed information on consent under GDPR is available from the [European Data Protection Board](#).

Please note that "health research" is defined broadly within the HRR. You should assess whether your Project does / does not fall within the scope of the HRR by reading the definition as set out in the legislation in full. If your research falls within the definition of health research you should ensure that the two separate elements of consent as defined above have been stated in the study Consent Form. Further information is available from the [Health Research Board](#).

Search: Proxy

This is consent given on a participant's behalf by another individual who is authorised to act on their behalf.

For example; proxy consent from a parent / legal guardian is required when the participant is a child. A Child is defined in the Children's Act 2001 (amended) and the Data Protection Act 2018 as "a person under the age of 18 years". Any research undertaken with participants who are children (or using data obtained from children) requires proxy consent.

Important - if you are recruiting individuals who are unable to give consent. The GDPR does not provide for anyone to give consent on behalf of another individual where that individual's capacity to consent is in question. You will need to apply to the [Health Research Consent Declaration Committee \(HRCDC\)](#) for a consent declaration. This application must be carried out in consultation with the Trinity College [Data Protection Officer](#).

Search: Assent

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 competent 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 appropriate instruments. 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. The Information Leaflet 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.

Search: Health Research

If your research is considered as Health Research, you must obtain explicit consent from participants unless one of the exemptions under the HRR amendments applies.

Health Research is defined in Regulation 2 of the [Health Research Regulations 2018](#) (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.

Search Data Retention

It is important to note that irreversibly and effectively anonymised data (i.e. data which cannot be used to identify an individual whatsoever) can be retained indefinitely. However, Anonymised Data should not be confused with Pseudonymised Data which is considered as personal data and subject to data protection law.

- *If the source data is not deleted at the same time that the “anonymised” data is prepared, where the source data could be used to identify an individual from the “anonymised” data, the data may be considered only “pseudonymised” and thus still “personal data”, subject to the relevant data protection legislation.*
- *Data can be considered “anonymised” from a data protection perspective when data subjects are not identified or identifiable, having regard to all methods reasonably likely to be used by the data controller or any other person to identify the data subject, directly or indirectly.*

Source: [Anonymisation and Pseudonymisation](#) - available from the Data Protection Commission.

Information on the length of time for which Personal Data will be retained must be indicated in the Participant Information Leaflet. If it is not possible to note the length of time, you must note how that period of time is determined (e.g. *“Research data will be retained on file for three years post-awarding of the PhD”*).

Researchers should consider all information that is being processed and ensure that the data is processed in compliance with data protection law. For example, contact details and signed consent forms constitute Personal Data.

Information on data retention is available in the Trinity College [Policy on Good Research Practice](#)

The Trinity College Records Management Policy and Records Retention Schedule is available [here](#).

For any research processing Personal Data (identifiable or coded), the open-access motto *“as open as possible, as closed as necessary”* is important. Personal Data should 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 Project for

periodic review of Personal Data, de-identification (pseudonymisation), anonymisation, archival, and / or erasure (if applicable).

The following is a non-exhaustive list of aspects to consider when calculating a retention period for Project data.

- If your project 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 deleted / anonymised.
- The timing of the anonymisation can have implications for participants, such as when a participant can request withdrawal or erasure of their Personal Data. When research data is anonymised and the master key to link the individual to their information is deleted, this data cannot be withdrawn. The participant should be made aware of this.
- The following are minimum data retention periods that are recommended for Personal Data and some further recommendations as to what would be good practice under GDPR regarding minimum retention periods for Personal Data and the protection of participants.
 1. For legal and regulatory reasons (medical or professional negligence, audit etc) - duration of study plus 7 years.
 2. For evidence reasons - i.e. novel IP etc, retain indefinitely.
 3. For compliance with funding body - retain for period of time requested by funder.
 4. To meet requirements of research contracts - retain for period of time specified in the contract.
 5. For academic assessment. E.g. Vivas and publication purposes (when verification or re-analysis etc. is requested) - retain for duration of study plus 3 years.

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. It is recommended that due diligence is carried out on the lawful basis for the primary data collection to ensure that the secondary processing is not incompatible with the original basis.

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

In projects that have interventions, are of moderate to high risk or have the potential to cause harm all information must be retained, including consent forms, codes and source data, so that it is possible to link back to the individual in case of any negligence claim.

Considerations when assessing how long you need to retain Personal Data:

- How many phases are in the Project?
- Do you need to be able to link information from different sources back to the individual participant?
- Do you need to verify the information?
- Is it possible that the information could be useful to other members of Trinity or your supervisor?

Remember that the participants can request deletion of their data at any stage before data has been pooled for analysis or published.

Details on limitations of withdrawal should be included 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 College storage recommendations.

Further Advice:

1. Data Protection Commission Advice on the Principles of GDPR - available [here](#).
2. For advice on data management. See CESSDA Data Management Expert Guide - available [here](#).

3. Data Protection Commission Advice on Anonymisation and Pseudonymisation- available [here](#).

If you are unclear about how long you should retain Personal Data, please contact your supervisor (if applicable) in the first instance. The Trinity College Research DPO can be contacted for further advice on retention of Personal Data at researchdpo@tcd.ie.

Search: 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 ([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.

Search: 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.

Search: Healthy Participants in a Health Trial

If you are conducting Health Research - see [Search: Health Research](#) - the [Health Research Regulations 2018](#) (amended 2021) will apply, even if the participants are recruited from a control group of individuals that are considered to be healthy.

“Healthy population” means participants recruited from the general population (e.g. through the community or a general source) 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.

Search: Processing Personal 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.

2.3.3 Research Sources and Sites

For each separate source / site of project data click in the “Add new site/ source” button 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.

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.

2.3 Research Sites & Data Sources

No data available in this section.

Research Sites and Data Sources
Please note that this is for Specific Sites where research is conducted eg. a school, hospital etc and/or Specific Sources eg. interviews. If research is not being conducted in a Specific Site or using a Specific Source then DO NOT click add data collection site/source
If research is being conducted in a Specific Site or using a Specific Source then DO click add data collection site/source and upload documentation confirming permission and/or ethical approval and any related DPIAs for each site and/or source.
[Search: Site Ethics](#)
[Link to Data Protection Impact Assessment \(DPIA\)](#)

Add Data Collection Site / source

New Ethics Site

2.3.1 Name data collection site/source *

2.3.2 Does this site / source require licence to use, access permission and /or ethics approval for this site/source *

Not applicable

Licence

Permission to access

Site / source ethics required and obtained

Site/ source ethics required but not yet obtained

2.3.4 Name source of permission (e.g. of licensor, ethics committee, person who grants permission to access site) or explain why permission is not required *

2.3.5 Was a DPIA required at this site/ source *

No

Yes

Name data collection site /source
<p>Does this site / source/ study require licence to use, access permission and /or ethics approval? (Select one)</p> <ol style="list-style-type: none"> 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 <p>NB. If you project requires both ethics and access, please merge these documents in the one attachment.</p>
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

NB. Links to definitions/further information

[Search: Site ethics](#)

Search: 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.

2.3.4 Outline of Project Methods

For each method/ measurement click in the “Add Methods and Measurements” button 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. Plan this carefully if you have only one of two measurements/ methods i.e. two different questionnaires, you can submit as two separate items and then you will be asked for two attachments. In larger studies with multiple methods / measurements appropriate bundles should be developed i.e., questionnaires, physical tests, biological samples etc., be careful to ensure that all relevant methods / measurements are included, as this may not come to light until the review phase and may cause delays.

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.

2.4 Outline of Project Methods

2.4.1 Outline the Data Collection Methods *

For each method employed, click on the add Methods and measurements, name it i.e. survey, focus group, blood tests



No data available in this section.

2.4.3 Does the project use any of the following methods? *



- Quality assurance studies
- Anonymous Surveys
- Unrecorded and anonymous observation of individuals in public areas
- Audits of standard practices or tests
- Information, documents or data which are in the public domain
- A data source not publicly available but which you have permission to use
- No

2.4.4 Does the project include an intervention? *

- No
- Yes

2.4.8 What is the approximate size of the target population? *

2.4.9 What is the proposed sample size -how many participants are involved in the study? *

Please estimate your population size see Guidance: Population


2.4.10 What is the justification for a sample size?

2.4.11 Outline the Method of Analysis (Word limit :100 words) *

Method measurement

TCD4.0.2.0

[Home](#) [Profile](#) [Submissions](#) [Reporting](#) [Administration](#)

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Create individual entries for each instrument, sample, measurement and test you will use.

When describing the instrument of data collection, indicate if the instrument 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.

Search: Low Risk Methods

Search: Audits of Standard Practice and /or Quality Assurance/ Quality Improvement Studies

Search: Intervention

Search: Target Population and Sample Size

Search: Methods

Search: Trial of Medicinal Products or Medical Devices/Apps

If conducting a trial of medicinal products or medical devices, apps please contact the Head of Clinical Sponsorship oversight [here](#) to establish if your trial can proceed. You will be provided with a letter of compliance to upload as an attachment in order for your ethical application to proceed.

[Add 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

NB. 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.

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

NB. If 1-4 selected this is a criteria that is needed for routing to Level 1

Does the project include an intervention? Yes/No

NB. 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 (including, psychology, social care)
- 2) Educational
- 3) Trial of a medicinal product or a medical device
- 4) Other

NB. If 3 is selected an attachment for a letter of compliance from the new [HSCO](#) is requested

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)

NB. Link to definitions/further information

[Search: Low risk methods](#)

[Search: Audits of standard practice and /or quality assurance/ quality improvement studies](#)

[Search: Intervention/Trial of Medicinal Product/Medical Device/App](#)

[Search: Target Population and Sample Size](#)

[Search: Methods](#)

Search: 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.

Search: Audits of Standard Practice/ Quality Assurance/ Quality Improvement

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.

Search: 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. For large research projects involving multiple methods and measurements you may find it easier to bundle methods together in the text box eg. Samples (blood, mucus, saliva) and then elaborate in a word document and upload as an additional attachment. Please note that the REAMs text fields do not accept diagrams so these will have to be uploaded as separate attachments 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.

Search: Intervention/ Trial of Medicinal Product/Medical Device/App

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.

If conducting a trial of a medicinal product or medical device/ app, please contact the Head of Clinical Sponsorship Oversight to establish if your trial can proceed-more information [here](#). You will be provided with a letter of compliance to upload as an attachment in order for your ethical application to proceed.

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.

Search: Target Population and Sample Size

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 directly or indirectly identifiable from the profiles of individual participants. For example; among the staff in a primary school, an individual may be identifiable by virtue of being the only member of staff 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 you should consider how to mitigate against possible identification of the participants.


2.4 Sampling and recruitment

This section will be included if the applicant indicates yes using primary sources i.e., collecting data from primary sources. Detail how you will select the sample


7.1 Sampling and Recruitment

7.1.1 Outline the sampling method * 


abc

7.1.2 Describe the time commitment of the participant * 


abc

7.1.3 Will the research require/use a gatekeeper * 


Yes
 No

7.1.4 Outline the position/role of the gatekeeper within the organisation 


abc


7.1.5 Detail the role of the gatekeeper in the project * 

abc

7.1.6 Is there a dependant relationship between the gatekeeper and the participants * 

Yes
 No

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7.1.8 Give a detailed step by step description of how participants will be recruited and append the recruitment material (Word limit: 100 words). * 

abc

Sampling & Recruitment

This section is required because you will be collecting data from primary sources.

[Search: Sampling method](#)
[Search: Time commitment](#)
[Search: Gatekeeper](#)
[Search: Recruitment](#)

Outline the sampling method *(Text field)*

Describe the time commitment of participants *(Text field)*

Will the research require/use a gatekeeper? Yes/No

NB. If answer is yes, this will enable the following questions

NB. 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

NB. 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)*

NB. Links to definitions/further information

[Search: Sampling method](#)

[Search: Time commitment](#)

[Search: Gatekeeper](#)

[Search: Recruitment](#)

Search: Sampling method

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.

Search: Time commitment

In order to give consent, participants need to understand the commitment they are making.

Search: 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?

Search: 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.

2.5 Animal Research

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

3.1 Animal Core Data

3.1.1 What setting/s will be used for data collection *

Laboratory
 In the wild
 Other

3.1.2 Describe the project including the taxa and species used and the sample size *

AS

3.1.3 Outline the potential benefits likely to derive from the project *

as

3.1.4 Describe the impact of the research on the subjects and their environment. Describe the mitigation of these impacts.

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3.1.5 Describe any risk to the researcher of carrying out the research. Describe the mitigation of these risks. *

As

3.1.6 Is this work covered by any externally held licence *

Yes
 No

Search Animal Research
The Section is required because your project involves animals.
[Search: Animal Research](#)

[Previous](#) [Next](#)

What setting/s will be used for data collection (*Multi selection select all that apply*)

- 1) Laboratory
- 2) In the wild
- 3) Other

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

NB. If the answer is Yes, this will add Licence to the attachments required for submission.

[Search: Arec/Animal Projects](#)

2.6 Health Research

This section will be included if the applicant indicated yes to the question Health research i.e. ,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.

9.1 Health Research

9.1.1 Please indicate which of the following apply to your Health Research project *

-- Please Select --

9.1.2 Is the PI a medical professional 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 where an intervention is part of the project protocol.

9.1.3 Will the project involve the administration of any substances or require participants to refrain from taking any substance *

Yes
 No

9.1.5 Will there be ongoing clinical supervision of the participants by a duly insured clinical practitioner during the project *

Yes
 No

9.1.6 Will the research participant's general practitioner be informed that they are taking part in the project *

Yes
 No

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Yes
 No

Health Related

This section is required because your research meets the definition in the Health Research Regulations 2018. Health Research generally requires Explicit Consent unless the conditions for an exception are met.

[Search: Health Research](#)
[Search: Informed Consent](#)
[Search: Explicit Consent](#)
[Search: PI and Insurance](#)
[Search: Consent Declaration](#)

[Health Research Regulations 2018](#)
[and Health Research Regulations Amendments 2021](#)

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

NB. 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.

NB. 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.

Is the PI a medical practitioner 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

NB. Only required if 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

NB. 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

NB. if the project gives the participant the choice to yes or no to the GP being informed, answer Yes to this question.

Will permission be sought from the research participants to disclose information (for example, information about adverse outcomes) to their GP? Yes/ No

NB. Links to definitions/further information

[Search: Health Research](#)

[Search: Informed Consent](#)

[Search: Explicit Consent](#)

[Search: PI and insurance/ Consent declaration](#)

[Health Research Regulations 2018](#)

and [Health Research Regulations amendments 2021](#)

Search: PI and Insurance and Consent Declaration

With respect to projects that include an intervention to be carried out within a designated state authority (e.g. HSE Hospital or Service) it is usually the case that a Principal Investigator ("PI") who is a medical practitioner will be insured by their organisation 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 sought from the [Health Research Consent Declaration Committee](#) (HRCDC). In such cases, when all other required revisions have been completed, the outcome will be given as. The project will be granted full approval when the Consent Declaration is authorised by the HRCDC, and a copy of the corresponding letter has been received and uploaded and then reviewed by the Research Ethics Committee.

2.7 Consent

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

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.

8.1 Consent

8.1.1 How will consent be obtained and by whom *

abc

8.1.2 Do your participants require support to give consent *

Yes

No

8.1.4 Do you require assent from participants e.g. because of their vulnerability *

Yes

No

8.1.7 Are you required to have garda vetting *

Yes

No

8.1.8 What is the time interval between giving information and securing consent? *

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8.1.10 Describe how you will inform participants about the use of their personal data *

abc

8.1.11 Describe how participants can withdraw their consent and/or their data *

abc

Consent

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.

[Search: Informed Consent](#)

[Search: Risk of Vulnerability](#)

[Search: Garda Vetting](#)

[Search: Time Interval](#)

[Search: Personal Data](#)

How will consent be obtained and by whom? <i>(Text field)</i>
Do your participants require support to give consent? Yes/No NB. If yes, a provide further information will appear NB. See Risk of Vulnerability for more information on support needs
Do you require assent from participants e.g., because of their vulnerability? Yes/No NB. If yes, a provide further information will appear.
How will assent be obtained and by whom? <i>(Text field)</i>
Are you required to have Garda clearance? Yes/No
What is the time interval between giving information and securing consent? (Select one) <ul style="list-style-type: none"> • less than 7 days • or more days NB. 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
Describe how participants can withdraw their consent and/ or their data

NB. Links to definitions/further information

[Search: Informed Consent](#)

[Search: Risk of vulnerability](#)

[Search: Garda vetting clearance](#)

[Search: Time interval](#)

[Search: Participants withdrawing from project](#)

Search: Garda vetting

It is a legal requirement that researchers who undertake research in which they will come in contact with children must complete the garda vetting process. If this requirement applies, you will be required to append up-to-date Garda vetting documentation (together in one document). It is the responsibility of the researcher/s to ensure that appropriate and up to date garda clearance is in place.

Search: 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.

Search: 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, such as interview recordings, data retained in a database or contained in a completed questionnaire, may be withdrawn by participants before anonymisation of data or before withdrawal of data would have a significant impact on the Project. For example; after data analysis in a qualitative study or after submission of thesis. Information regarding when participant data can be withdrawn should be included in the in the Participant Information Leaflet.

Participants can request the erasure of their Personal Data at any time up until the point the data has been pooled for analysis or is ready to be published. The right to erasure is not absolute and is subject to certain restrictions. Details on limitations on erasure of data, should be included in the in the Participant Information Leaflet. Further information on the right to erasure is available from the Data Protection Commission [website](#).

2.8 Risk

2.8.1 Risk or Harm to the Researcher

After you have completed the first question click the button for add risk. This section is mandatory for all projects. Click on the add button below for each researcher risk, select the risk and estimate impact, likelihood and mitigations. Enter each risk separately by submitting the first risk and selecting the add button again to add more, if applicable.

Risk to Researcher

Please note this risk section is about exploring risk to participants, researchers and the site where the research is conducted. This is not about data risk which, if relevant to your application, can be covered in the data protection section, if it opens up.

Search: [risk](#), [harm to researcher](#)

[Lone Working Policy](#)

Add Risk

Researcher Risk

4.1.3 Identify the risk from the list below ? *

-- Please Select --

4.1.5 Estimate the impact *

-- Please Select --

4.1.6 Estimate the probability/ likelihood *

-- Please Select --

4.1.7 Detail the mitigation measures *

Submit

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

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

NB. If other elaborate

NB. If none is selected the following additional question will be blocked out and the box is ready to press submission

NB. Links to definitions/further information

[Search: Risk, benefit, harm to researcher, participant, environment and society.](#)

[Search: Lone worker](#)

[Ethics Guidelines & Declaration for Interviewing or Testing Adults \(2020-21\)](#)

Are you a school of psychology applicant interviewing and or testing with adults? Yes/No

This question is for School of Psychology only

NB. If the answer to this question is yes the applicant will be required to append [Ethics Guidelines & Declaration for Interviewing or Testing Adults \(2020-21\)](#)

[Search: 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 or 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.

Search: 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](#).

2.8.2 Risk, harm to site, environment, or society

After you have completed the first question click the button for add risk. This section is mandatory for all projects.

Click on the add button below for each risk, select the risk and estimate impact, likelihood and mitigations.

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

4.2 Risk or harm to site, environment or society

No data available in this section.

Risk to Site, Environment and Society

Please note this risk section is about exploring risk to participants, researchers and the site where the research is conducted. This is not about data risk which, if relevant to your application, can be covered in the data protection section, if it opens up.

Search: [risk](#), [harm to site](#), [environment](#), [society](#)

Add Risk

Site Risk

4.2.1 What (if any) are the potential risks to the data collection site (include confidentiality of site), environment or society. *

-- Please Select --

4.2.2 Estimate the impact *

-- Please Select --

4.2.3 Estimate the probability/ likelihood *

-- Please Select --

4.2.4 Detail the mitigation measures *

Submit

Identify the risk from the list below

- Risk to environment, site or society
- None

NB. If none is selected the following additional question will be blocked out and the box is ready to press submission

All the risks in this instance can be submitted using one submission. Consider this carefully, many studies may not have significant risks relating to Site, Environment and Society. consult your local REC documentation for advice and examples. One of the most common risks that should be cited, if necessary, in this section is the potential revelation of the site/s names directly or indirectly in the published documentation. If this applies, you must ensure that representative of the site have been consulted, and that any appropriate mitigation procedures have been implemented.

NB. Links to definitions/further information

[Search: Risk benefit harm to researcher, environment, and society.](#)

2.8.3 Risk to participant

After you have completed the first question click the button for add risk. This section is mandatory for all projects. Click on the add button below for each participant risk, select the risk and estimate impact, likelihood and mitigations. Enter each risk separately by submitting the first risk and selecting the add button again to add more, if applicable.

4.3 Risk or harm to participants

4.3.1 Do you or any of the research team have any dependant relationship to the participants? * [?](#)

Yes
 No

4.3.2 Detail the role of the researcher/s in the project, the relationship of the researcher/s with the participants normally, and how you will mitigate against coercion of participants to participate in the project or in influencing their responses * [?](#)

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No data available in this section.

Risk to Participant

Please note this risk section is about exploring risk to participants, researchers and the site where the research is conducted. This is not about data risk which, if relevant to your application, can be covered in the data protection section, if it opens up.

Search: [Dependant relationship](#)
Search: [Participant risk](#)
Search: [Conflict of Interest](#)
Search: [Revealing information](#)

[Add Risk](#)

Participants Risk

4.3.3 Identify the risk from the list below ? *
-- Please Select --

4.3.5 Estimate the impact * 4.3.6 Estimate the probability/ likelihood *
-- Please Select -- -- Please Select --

4.3.7 Detail the mitigation measures *

[Submit](#)

Do any of the research team have a dependant relationship to the researcher?

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

NB. If none is selected the following additional question will be blocked out and the box is ready to press submission.

2.8.4 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.

Outline any direct benefits of participation to research participants

2.8.5 Conflict of Interest

Conflicts of Interest arising from project funding will be dealt with separately and should not be entered here

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

NB. If yes give details of the Conflict of Interest and what mitigation measures are in place

NB. Links to definitions/further information

[Search: Dependant relationship](#)

[Search: Participant risk](#)

[Search: Revealing information/Disclosure](#)

[Search: Benefits](#)

[Search: Conflict of interest](#)

[Search: 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 require 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.

Search: Revealing information/Disclosure

There are certain circumstances in which the researcher, due to a professional requirement or otherwise, may be obliged to disclose the information revealed by a participant to relevant third parties, for example; An Garda Síochána.

Disclosure may relate to concerns relating to physical, emotional, and / or sexual abuse, concerns for child protection, any disclosure concerning rape, self-harm or suicidal intent, criminal activity or malpractice /negligence.

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 appropriate authorities in accordance with the Trinity College Child Protection Policy.”*

Search 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.

Search: 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](#))

2.9 Funding

This section is required because you have indicated that your project is funded.

6.1 Funding

6.1.1 Insert RPAMS number if applicable and available [🔗](#)

6.1.2 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 * [🔗](#)

6.1.3 Specify any funder specific requirements or obligations which should be brought to the attention of the ethics committee and/ or Trinity Innovation and Enterprise * [🔗](#)

6.1.4 Will the results of the project be used or disclosed for commercial purposes * [🔗](#)

Yes
 No

6.1.5 Please clarify which party shall have the commercialisation and/or intellectual property rights * [🔗](#)

Funding
This section is required because you indicated that this project is funded.

[Search: RPAMS Number](#)

[Search: Sources of Funding](#)

[Search: Conflict of Interest \(Funding\)](#)

[Search: Disclosure](#)

[Search: Commercialisation](#)

6.2 Conflict of Interest

6.2.1 Are you aware of any possible Conflict of Interest arising from the funding or commercialisation of this project * [🔗](#)

Yes
 No

6.2.2 Give details of the Conflict of Interest and what mitigation measures are in place * [🔗](#)

6.2.3 Is there likely to be possible Conflict of Interest between the funders of the project and the aims and results of the project * [🔗](#)

Yes
 No

6.2.4 Give details of the Conflict of Interest and what mitigation measures are in place * [🔗](#)

[Previous](#) [Next](#)

Insert RPAMS number if applicable and available

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)*

<p>Please specify any funder specific requirements or obligations which should be brought to the attention of the ethics committee and or Trinity Research & Innovation <i>(Text field)</i></p>
<p>Will the results of the project be used or disclosed for commercial purposes? Yes/No</p>
<p>NB. Follow up question if answer is yes:</p> <p>Please clarify which party shall have the commercialisation and/or intellectual property rights. <i>(Text field)</i></p>
<p>Conflict of interest</p>
<p>Are you aware of any possible conflict of interest arising from the funding or commercialisation of this project? Yes/No</p> <p>NB. If yes: Give details of the Conflict of Interest and what mitigation measures are in place</p>
<p>Is there likely to be possible conflict of interest between the funders of the project and the aims and results of the project. Yes/No</p> <p>NB If yes: Give details of the Conflict of Interest and what mitigation measures are in place. <i>(Text field)</i></p>

NB. Links to definitions/further information

[Search RPAMS Number and Sources of funding](#)

[Search: Conflict of Interest](#)

[Search: Disclosure re Funding/Declaration of Interest](#)

[Search: Commercialisation](#)

[Search: 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 Innovation & Enterprise 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 Trinity Innovation & Enterprise.

This occurs when a person's judgement concerning a primary interest could be unduly influenced by a secondary interest which in the case of funding might include benefits in kind, or where the participant is being paid more than the accepted gratuity for taking part, or where more than one source of funding for exactly the same proposal has been offered. There is nothing inherently unethical in finding oneself in a position of conflict of interest; what is required is to recognise the fact and deal with it accordingly. More information is available in the [Good Research Guide](#)

[Search: Disclosure re Funding/Declaration of Interest](#)

An obligation is placed on the recipients of all research grants to declare any interest that would interfere with or compromise the performance of research supported by the grantor. This is to ensure the technical integrity and

impartiality of the researcher's work. This will involve completing a [Declaration of Interest](#) document that is to be signed at contract signature stage. More information is available at: [Good Research Guide](#)

Search: Commercialisation

Guidelines and advice on any likely commercialisation opportunities arising out of TCD research, ie TCD Intellectual Property are available in the Policy, Practice and Regulations on Intellectual Property -2018 available [here](#)

2.10 Human Biological Samples

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

5.1 Human Biological Samples

5.1.1 Will the samples in any form be stored for any period after the project completion * ⓘ

Yes
 No

5.1.2 State what type of samples will be stored * ⓘ

xyz

5.1.3 State where they will be stored (name specific location, ownership etc.) * ⓘ

abc

5.1.4 Planned date of destruction of sample * ⓘ

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iic TCD4.0.2.0 Home Profile Submissions Reporting Administration Welcome Corrinna Moore

No

Biological Samples
Search: Biological Samples.

Previous Next

Will the samples in any form be stored for any period after the project completion? Yes/No.

NB. If yes, the next three questions will be generated

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

[Search: Biological Samples](#)

[Search: Biological samples](#)

Careful consideration and respect are required in the gathering, storage and destruction of biological samples of all types and examples. Care and consideration is required at all times and in all instances; e.g. when dealing with small quantities of hair samples or complete organs. Care should be taken when managing such samples and when processing records relating to such samples. In non-longitudinal studies, particularly when samples are anonymised (i.e. no key to link to an individual), it is best practice that biological samples are destroyed as soon as is feasible in accordance with the [College Records Management Policy](#) for research records of this nature.

In addition, if the biological sample relates to a living individual who can be directly or indirectly identified you will need to consider the processing and retention implications under data protection law.

2.11 Data protection

The Data Protection Office review and approval process is NOT integrated in the REAMs platform.

If you missed the new process at the beginning of your application you can get the detail [here](#). If your application is affected you will receive a pop up in this section advising you on steps to take to achieve a Data Protection Review for your project.

Your application is now paused. There are data protection implications for your research which will require **review** from the Trinity College Data Protection Office before you can continue with this application. Please contact the Research Data Protection Officer at dataprotection@tcd.ie and include 'REAMS APPLICATION QUERY' in your email subject line. ✕

Please note you will be required to upload an attachment 'DPO Review-Letter of Completion' to your application' in order to proceed with your application in REAMs.

NB. You will NOT be able to submit your application to the REC until you have completed your data protection review with the DPO as you need a DPO letter of completion to upload against the attachment request.

11.1 Application Attachments


The following attachments are required before submission

- DPO review-letter of completion

2.11.1 Opening questions


This section is required because you are processing personal data (including pseudonymised data) that could directly or indirectly identify a participant. Trinity staff and students who will process personal data must complete data protection (GDPR) training.

10.1 Opening Questions

10.1.1 Have all Trinity researchers (staff and students) in this project completed the College Data Protection GDPR training module? * 

-- Please Select -- 

Review guidance before answering

10.1.2 Are all Trinity Staff and Trinity Students working on the project familiar with the Trinity College Personal Data Breach Procedural Guidelines? * 

Yes

Application cannot proceed unless the answer to the question is 'Yes'

Opening Questions

This section is required because your Research Data contains information that could directly or indirectly identify a participant. Trinity staff and students who will process personal data must complete data protection (GDPR) training.

[Trinity Breach Procedural Guidelines](#)

Search: Data Protection Opening Questions

Refer to GDPR training module and Research Integrity Training

Have all Trinity researchers (staff and students) in this project completed the College Data protection GDPR training module? Yes/No

Are all Trinity Staff and Trinity Students in this project familiar with the Trinity College Personal Data Breach Procedural Guidelines?

NB. Your application cannot proceed unless the answer to the question is 'Yes'

2.11.2 Data Protection Information

10.2 Data Protection Information

10.2.1 What is Trinity's role in the project? * ⓘ

-- Please Select --

10.2.2 How many participants' Personal Data are being processed in this project? * ⓘ

-- Please Select --

10.2.3 List all types of Personal Data (including any special category or sensitive personal data) that you will process during the lifecycle of the project? * ⓘ

10.2.4 Does the project involve processing of special category data or data relating to criminal convictions and/or offences (sensitive personal data)? * ⓘ

No

Yes

10.2.5 Is the Personal Data shared outside the research team with any other units within Trinity College? * ⓘ

Yes

No


10.2.7 Is this data shared with any third party outside of Trinity ? ⓘ

Yes

No

10.2.9 Describe what IT due diligence you intend to carry out or have carried out on these organisations. ⓘ

10.2.10 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 are backed up etc. ⓘ

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Yes

No

10.2.12 Detail how long Personal Data will be retained for in an identifiable or coded format. ⓘ

Data Protection Information

Trinity as an organisation may be the data controller or data processor dependent on staff and student's role in the project. Detail how information is shared within Trinity, with external third parties and with parties outside the EEA/EU as applicable.

Search: [Data Protection Information](#)

What is Trinity's role in the project? (Drop down menu)

- Controller
- Joint controller
- Processor

How many participants' personal data are being processed in this project? (Drop down menu)

- ≥100
- <100

List all types of personal data (including any special category or sensitive personal data) that you will process during the lifecycle of the project. (Text field)
Does the project involve processing of special category data or data relating to criminal convictions and/or offences (sensitive personal data)? Yes / No
Is the personal data shared outside the research team with any other units within Trinity College? Yes / No
Name these units (Text Field) Detail what personal data will be shared with them and why
Is the personal data shared with any third party outside of Trinity? Yes/No
Provide names of these organisations and detail what personal data will be shared with them and why. (Text Field)
Describe what IT due diligence you intend to carry out or have carried out on these organisations (Text Field)
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 are backed up etc
Are the personal data transferred outside of the UK &EEA? Yes/No NB. If yes, you must contact the Data Protection Office.
Detail how long the personal data will be retained for in an identifiable or coded format. (Text field)

2.11.3 Processing risk

All projects that have personal data in their research will be presented with this section, there the applicant will assess each risk in terms of likelihood and impact and describe how it will be mitigated for. Each risk is added separately by clicking on the “ add processing risk button.

10.5 Processing Risk

No data available in this section.

Processing Risk

Search: Data Protection Processing Risk

Add Processing Risk

Processing Risk ✕

10.5.1 List the processing risks of any kind *

10.5.2 Severity / Impact * **10.5.3 Likelihood ***

-- Please Select --

-- Please Select --

10.5.4 Solutions/Mitigation Actions *

Submit

2.11.4 Closing section

Provide details that you believe to be relevant, but which have not been asked in this section.

10.6 Closing Section

10.6.1 Include any additional information in respect of the study which may be relevant * ⓘ

Closing Section
Provide details that you believe to be relevant but which have not been asked in this section

Include any additional information in respect of the study which may be relevant.

Links to definitions/further information

[Search: Data protection office: Opening Questions](#)

[Search: Data Protection Office: Data Protection Information](#)

[Search: Data Protection Office: Data Protection Processing Risk](#)

2.12 Attachments

In REAMs, as you work your way through the application form, the answers given to certain questions will determine whether attachments are required or not. These may be generic or specific attachments (where a site, location, method or person is named within brackets) in nature.

2.12.1 Required Attachments

The attachments required are listed in the pink box below. It is necessary that each attachment is added in turn. As this happens, the request clears out of the pink box. All attachments must be uploaded before submission can occur.

11.1 Application Attachments

The following attachments are required before submission

- Research Integrity Module Certification
- Data Protection Training certificate
- Informed Consent Form
- Recruitment Documentation

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File name

The names of the 'uploaders' will be visible to the applicant-reviewers MUST NOT upload their feedback directly here but rather email it to the REC to upload

File description

The names of the 'uploaders' will be visible to the applicant-reviewers MUST NOT upload their feedback directly here but rather email it to the REC to upload

11.1.3 Document type

11.1.4 Select Item

Only use this field if the attachment requested has a specific item (site, person, method) within brackets

The help text to direct you how to clear an attachment is detailed below:

Application/Submission Attachments

To upload an attachment follow these steps:

1. File name: select the file to upload ensuring the REAMs reference number is in the file name
2. File name description: the name you want to give the file
3. Document type: choose from the drop down menu the direct match to the one requested
4. Please select which item this attachment applies to: choose from the drop down menu the specific person, site or item (will be within brackets).
5. Click Upload: clears the attachment request

To delete an attachment, click on Delete (bin icon) in the Actions column

Please note that attachments can be sorted by date of upload by clicking on the 'Uploaded on' column.

Also each version of the application form uploaded is automatically saved as an attachment.

In addition, review uploads land here and can be distinguished from application attachments by the file name and upload date only.

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.

NB. It is important to put the reference number (unique number given to your application even in draft form) in the file name for all your associated attachments

- 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 generic types of documents that could be uploaded in alphabetical order, select the one that reflects the document you have just selected to upload eg. Consent Form.
- 4) Please select which item this attachment applies to: a further step to 30 is required for attachments that are affiliated to a specific person, site or item (signified in brackets after the attachment listed in the pink box). Scroll through the selection given and select the name/site/ item that is appropriate in each case.
- 5) Click the upload button and the attachment will be removed from the list.

NB. Continue with the same procedure until all the attachments are uploaded.

2.12.2 Optional Attachments

Also note that it is possible to upload optional attachments outside of those required above to further supplement the information in your application such as:

- measurement diagrams (REAMs text boxes cannot accommodate diagrams)
- lengthy protocols
- more detail on methods/measurements where they have been bundled to fit the online form .

The process for uploading is exactly the same as that for required attachments and remember to name the attachment files with the unique identifier code from the application.

NB. Follow steps 1-5 but select 'other documentation' from the drop down menu under document type in step 3

11.1.3 Document type

Other Documentation ▼

2.12.3 Participant Information Leaflet

A Participant Information Leaflet (PIL) is required as an attachment only if you are recruiting participants. There are three possible PILs that you may upload against the PIL attachment request. The one you choose depends on the nature of your research. There is a link to these in the help text on the REAMs application:

- PIL where Personal Data is not subject to DPO approval: contact your REC for a school specific template
- PIL where Personal (Health) Data is processed: [link to template here](#)
- PIL where Personal (Non-Health) Data is processed: [link to template here](#)

It is also important to consider the format, style, language and length when completing a Participant Information Leaflet to optimise accessibility and understanding:

- 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.](#)
- The length of the PIL is also important to consider.

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. 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.

3. Other Features

3.1 Declarations

These declarations represent a digital signature of those involved in the research project and is essentially the signing off on the project. A slider button is triggered as an acceptance by the research team member: applicant, supervisor, PI.

3.1.1 Applicant's declaration

Confirm and Submit Ethics Application

Signatures and Final Page

I hereby declare that the details provided in this application accurately reflect the research proposal. I confirm the documents have been prepared to comply with Good Research Practice, Data Protection Legislation, including the Health Research Regulations (where appropriate), and Trinity College policies and regulations. I undertake to carry out the research as described and will seek further approval if substantive changes to the research are proposed after this submission. I will report any adverse events or serious complaints, return all required reports and process research project data in compliance with Trinity College policies and regulations and relevant legislation.

Confirm and Submit Ethics Application
This section is required for all projects

Cancel Submit

I hereby declare that the details provided in this application accurately reflect the research proposal. I confirm the documents have been prepared to comply with Good Research Practice, Data Protection Legislation, including the Health Research Regulations (where appropriate), and Trinity College policies and regulations.

I undertake to carry out the research as described and will seek further approval if substantive changes to the research are proposed after this submission.

I will report any adverse events or serious complaints, return all required reports and process research project data in compliance with Trinity College policies and regulations and relevant legislation.

3.1.2 PI declaration

Your Approval and Comments

I hereby declare that the details provided in this application accurately reflect the research proposal. I confirm the documents have been prepared to comply with Good Research Practice, Data Protection Legislation, including the Health Research Regulations (where appropriate), and Trinity College policies and regulations. I undertake to carry out the research as described and will seek further approval if substantive changes to the research are proposed after this submission. I will report any adverse events or serious complaints, return all required reports and process research project data in compliance with Trinity College policies and regulations and relevant legislation.

Update Status To:

Send back to applicant to make revisions

Send to REC for ethical review

I hereby declare that the details provided in this application accurately reflect the research proposal. I confirm the documents have been prepared to comply with Good Research Practice, Data Protection Legislation, including the Health Research Regulations (where appropriate), and Trinity College policies and regulations.

I undertake to carry out the research as described and will seek further approval if substantive changes to the research are proposed after this submission.

I will report any adverse events or serious complaints, return all required reports and process research project data in compliance with Trinity College policies and regulations and relevant legislation.

3.1.3 Supervisor declaration

Your Approval and Comments

I have reviewed the documents and confirm they comply with Good Research Practice, Data Protection Legislation, including the Health Research Regulations (where appropriate), and Trinity College policies and regulations. I undertake to ensure that the research study will be conducted in line with the approval received both from the Research Ethics Committee and the Data Protection Office. I will seek further approval if changes are proposed to the research after this submission. I will report any adverse events or serious complaints, return all required reports and process research project data in accordance with Trinity College policies and regulations and relevant legislation.

Update Status To:

Send to REC for ethical review

Send back to applicant to make revisions

I have reviewed the documents and confirm they comply with Good Research Practice, Data Protection Legislation, including the Health Research Regulations (where appropriate), and Trinity College policies and regulations.

I undertake to ensure that the research study will be conducted in line with the approval received both from the Research Ethics Committee and the Data Protection Office. I will seek further approval if changes are proposed to the research after this submission.

I will report any adverse events or serious complaints, return all required reports and process research project data in accordance with Trinity College policies and regulations and relevant legislation.

3.2 Word Download /Application Versions

Although it is possible to download a word copy of your application and the corresponding attachments, a copy of the application is automatically saved when it is submitted and can be found in the attachment section. In fact, each subsequent submission is also saved and can be identified by both the date of the submission and the version number (the first submission is version 1).

File name	Document Type	Related To	Ver	Uploaded On	Actions
Application Form 22/09/2023.docx			3	22/09/2023 17:31	↓
Application Form 22/09/2023.docx			2	22/09/2023 16:09	↓



The attachments associated with the application are also saved and have a version number associated with them.

File name	Document Type	Related To	Ver	Uploaded On	Actions
Document.docx	Research Integrity Module Certification		1	21/09/2023 17:13	↓
Document.docx	Data Protection Training certificate		2	22/09/2023 16:08	↓
Document.docx	Consent Form		1	21/09/2023 17:11	↓

3.3 Status, Notifications & Outcomes

3.3.1 Status

You can follow your application as it progresses through the review and approval process by clicking on your submissions page, finding your submission (by searching by project title or its reference number) and looking at the status. The version number and submission date are also displayed here.

REF#	Title	Risk	REC	Submission Date	Status	Versions	
1347	Branching Test MP Lavergne Marie Lavergne	2	School of Medicine	18/10/2022	With Principal	1	 

Possible Status Indicators:





- 'With Primary Supervisor' – student application requires supervisor approval
- 'With Principal' – applicant is not the PI and requires PI approval
- 'Awaiting Recommendation' – the application has landed with the REC and reviewers are not yet assigned
- 'Awaiting Reviewer Feedback' – reviewers are assigned but have not yet completed their reviews
- 'Awaiting Approval' – the reviews are completed and are back with the REC but the final outcome is not yet decided
- 'Draft' – not yet submitted (Version 1) OR requires revision by applicant (Version 1 + number of times application been submitted eg. Version 2 if 2nd submission
- 'Approved'
- 'Rejected'

You can do an audit trail of where your application has been/is on the approval journey by clicking on the person/head and shoulders icon to the right of the submission summary. A date, time stamp and green tick signifies that the application has been through that stage.

Test 25/10 With Primary Supervisor Back

PI: Shafiq Far
Risk Level: 2

nic TCD4.0.2.0 Home Profile Submissions Reporting Administration Logged in as: Shafiq Far

Ethics Project Principal Corrinna Moore	02/11/2023 2:01:16 PM	
Ethics Supervisor Saadi Shahin Current Approver		
Ethics Rec Admin Laavanya Parthasarathi		
Ethics Rec Admin Vincent Kelly		

3.3.2 Notifications and Tasks

At each stage of the approval process the applicant will receive notification, via a personal email, and a notification alert, on their REAMs home page, signifying a change in status of their application.

The screen below shows the Notifications and Tasks view on the home page which has a notification alerting the applicant that an application requires action. The live link takes them to the application.

(i) Notifications

The screenshot shows the 'Notifications and Tasks' interface. At the top, there are tabs for 'Notifications' (59) and 'Tasks' (10). A search bar is present. Below is a table of notifications:

Subject	Actions
Ethics Application "Test 21st Sept" has been approved New	
Ethics Application "Test 21st Sept" has been submitted New	
Ethics Application "Test 21st Sept" requires amendments New	
Ethics Application "Test 21st Sept" has been submitted	
Ethics Application "Test 13th Sept" has been approved New	
Ethics Application "Test 13th Sept" has been submitted New	
Ethics Application "Test 13th Sept" requires amendments New	
Ethics Application "Test 13th Sept" has been submitted New	

At the bottom, there is a pagination control showing 'Showing 1 to 10 of 64 entries' with page numbers 1 through 7 and a 'Next' button.

(ii) Tasks

The screenshot shows the 'Notifications and Tasks' interface with a task card. At the top, there are tabs for 'Notifications' (59) and 'Tasks' (10). A search bar is present. Below is a table of tasks:

Ref #	PI	Title	Approval Step / Role	Notification	Date	link
7366	Niveen El-Far	test	Ethics Supervisor	Hello, The following ethics application has been submitted and requires	20/10/2023 11:59	

Below the table is a detailed view of the task card for Ref # 7366. It includes the following information:

- Application Number for reference below:
 - Title: test
 - PI: Niveen El-Far
 - Reference No: 7366
- Please try to complete your approval stage of this application within 2 weeks of receipt of it.
- Please login to

3.3.3 Review Outcomes

In addition, there are several possible outcomes to an ethical application. You can see these by clicking on the person/head and shoulders icon visible to the right of the submissions view:

REF#	Title	Risk	REC	Submission Date	Status	Versions	
7465	Checking DTP Cert Shafiq Far	3	Faculty of STEM	05/10/2023	Approved	3	

As well as giving an audit trail of where your application has been is (with reviewer names withheld) this summarises the feedback from the REC which will be visible in the add comment box.

The screenshot shows the 'Add Comments / Files' form. At the top, there are tabs for 'Existing Comments' and 'Upload Attachments'. Below is a text area for 'Comments' with a placeholder text: 'The names of the 'uploaders' will be visible to the applicant-reviewers MUST NOT upload their feedback directly here but rather email it to the REC to upload'. A 'Submit' button is located at the bottom right of the form.

- Approve: the application has been successful, and approval granted

- **Reject:** the application has been refused
- **Make Revisions:** the application has been reset to draft enabling you to do minor or major corrections

NB. For making revisions look out for attachments that may have been uploaded summarising the changes being asked for: a cover letter from the REC, uploaded as an attachment; a word document, perhaps the word copy of the application and/or its attachments with comments.

3.3 Revisions

If revisions are required by the ethics committee, the application is ‘reset to draft’ so that the applicant can make the revisions.

NB: The REC feedback will direct you to the section/question number to be addressed and when you do the revisions, the fields changed are highlighted by a red icon so that the reviewer can easily check that you have done the revisions.

It is advised that revisions be summarised by the applicant in a cover letter that can be uploaded as an attachment as ‘other documentation’

3.4 Amendments

These are defined as changes that arise after a research project has been already approved.

To begin an amendment click on ‘New Ethics Application’ , verify the checklist and select ‘Amendment’ and a pop up appears summarising what constitutes an amendment.

Ethics

New Ethics Application

Search:

New Ethics Review ✕

Not all research on humans and/or their data or animals requires ethical approval. Check if your research requires ethical approval by referring to this set of criteria [here](#).

Please note that your application may require assessment from the College Data Protection Office. This could result in an extended application process which should be considered from the outset. Please review the information provided [here](#) before commencing your application

I confirm that I have checked the relevant criteria and reviewed the new data protection process

Project Title *

Application Type *

Please note that, amendments are for small changes to your research, anything significant will necessitate a new application. In the case of an amendment, some attachments may need to be uploaded again even if they are not part of the change-the system will make this clear-please see Help Text in the attachments section.

Another pop-up appears giving you a list of existing applications, choose the one you wish to amend, then make sure to put this in as the project title so that both the amendment project title and the exiting application share the same name. The fields in the amendment will automatically auto-populate from the original application and is badged 'amendment' to signify this, make the changes to the relevant sections and resubmit.

REF#	Title	Risk	REC	Submission Date	Status	Versions
7484	bla Corrinna Moore Amendment	3	Health Policy Management / Centre for Global Health		Draft	1

Some specific item attachments (named person, site,method) may need to be re-uploaded prior to submission.

Amendment Attachments Please note that, in the case of an amendment, some attachments uploaded against 'specific item' entries within the submission (e.g. Measurements, Team Members, etc) may need to be uploaded again even if they are not changed. In this case, the system will prompt the user to upload these. You must delete the original of these requested attachments and upload their replacements as requested. General attachments against the submission do not need to be reuploaded unless of course they are part of the changes in the amendment and in such cases they will be requested by the system.

NB. Amendments are for small changes to your research

- 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.

NB. Small changes to the wording of an interview schedule, for example, do not require that an amendment be submitted, unless the content explored is substantially different. Any significant change requires a new application.

3.5 Post Approval

After approval has been granted, an approval letter is automatically generated by the system and can be found in the attachments section of the application where it can be downloaded.

File name	Document Type	Related To	Ver	Uploaded On	Actions
Application Form 22/09/2023.docx			3	22/09/2023 17:31	↓
Application Form 22/09/2023.docx			2	22/09/2023 16:09	↓
Approval Letter- 7427 22/09/2023.doc			4	22/09/2023 19:09	↓

This letter reminds the applicant that they are responsible for ensuring that the research is carried out according to the ethical principles approved and within GDPR law. It also states that the ethics approval is valid for the time lines recorded in the application only (any changes must be applied for in an amendment) and reminds the applicant that they are responsible for all post approval requirements and it directs them to where to get these forms [here](#):

- Adverse events: reminding them of the need to report these immediately
- End of project report: to summarise the research outcomes
- Annual report: if the research is still going more than one-year after the granting of approval a report summarising progress is required

Appendix 1: Participant Information Leaflet: For Projects that do not require DPO approval

A Participant Information leaflet remains a requirement even when research studies do not entail the collection or processing of personal data. Contact your REC for a school specific template.

Researchers should pay attention to:

- 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.

It is critical that the contents of the Participant Information Leaflet match the details provided in the Application Form.

Appendix 2: Guidelines For Interviewing or Testing Adults

School of Psychology, Trinity College Dublin

(See separate guidelines for research with children)

These guidelines must be read by all staff and students carrying out research on human participants in the School of Psychology, Trinity College Dublin. The School's Research Ethics Committee will not accept an application for ethics approval unless a declaration is signed saying that the applicant has read, and will abide by, these guidelines.

Know how to get help: If you feel under threat, immediately remove yourself from the situation and call security on extension 1999 (01 896 1999 from a mobile phone).

IN THE SCHOOL

Under most circumstances, testing of participants proceeds without incident. Occasionally, however, difficulties arise and these guidelines should be followed by all students and staff.

If you are interviewing or testing a participant in the School/TCIN/Centre for Global Health, notify them in advance that they will be required to show photo ID (student card, driver's license, public services card) upon arriving for their appointment. When the participant arrives, have them present their ID and sign in to the participant sign-in book (available at reception of SoP/security of TCIN and Global Health). This requirement applies to all participants (i.e., TCD students and non-students).

Students/staff must work in pairs when interviewing or testing participants outside office hours (i.e., after 5.30pm).

When testing participants who are not students of the College, it is strongly recommended that testing be performed in the more populated areas of buildings (e.g., on the first floor in AAP, rather than on the ground floor).

If you are interviewing or testing a participant in the School, please make sure that you have a telephone number and address for them before they come in. Please telephone in advance to confirm that this is a correct number. Ensure that this is filed in a place known to your project supervisor or to a colleague.

Make sure that someone knows that you are seeing this person, where, and when you are due to finish. Please introduce the person by name to this colleague.

Please dress appropriately and somewhat conservatively and not in a way that could make anyone of a different age, background, or gender feel uncomfortable.

Wherever possible, try to ensure that you are seated nearest the door. If practical, leave the door slightly ajar. As some of the testing cubicles do not have telephones, bring your mobile phone with you.

If you have any doubts or worries about the person, terminate the session immediately and inform your supervisor. It may be better to leave the room and to let the person finish while reporting the difficulty to your supervisor, the School's Safety Officer (Lisa Gilroy – Ext 1091) or the Head of School, Prof David Hevey. Please make sure you inform all of these people of the difficulties after the event.

If you feel under physical threat, immediately leave the room and call security on extension **1999 (01 896 1999** from a mobile phone or a non-College landline).

Should you see anyone in the building whom you regard as behaving suspiciously, or in the School whom you do not recognise, do not confront but immediately leave the building, seek assistance from any available source and phone security on extension 1999.

Researchers should report any cases of inappropriate or persistent calls or contact from participants to the supervisor, Safety Officer and Head of School.

If any participant asks for help or advice for psychological or other problems, please say firmly that you are not qualified to give such advice and tell them to contact their GP or go to a local hospital casualty department.

ASSESSMENTS OR INTERVIEWS OUTSIDE THE SCHOOL

For undergraduates, a first home visit must always be made by two people. The second person's name and their role need to be declared on the Ethics Application Form. Per SPREC Guidelines for Research with Children, all researchers working with minors (i.e. any person under 18 years of age) and vulnerable populations must have obtained Garda Clearance.

For all other postgraduates and staff, the following precautions must be taken when making a home visit:

Staff/students must always carry a charged mobile phone.

There should be a clear 'checking-in' procedure to a member of staff (this includes postdoctoral research fellows) when they have been on a home visit. The member of staff must have a record of the time of the visit, the name and address, and the telephone number. They must also know the mobile phone number of the researcher.

As part of the introduction to the person being assessed, the researcher should say 'I just have to call my supervisor. The researcher should then ring the designated staff in the presence of the participant and say 'I'm in xxx's house, and will be finished at approximately xx'.

If a researcher fails to ring the designated staff member at the appointed time, that staff member should immediately try to make contact with him/her. Failing that, a more senior member of staff should be contacted, and where appropriate, the relevant emergency services telephoned.

Make sure you that are familiar with routes to and location of your destination.

Guidelines for Assessing Adult Patients with Brain Injury or a Psychiatric Condition

Patients/participants should be well briefed about what to expect of the testing session before the visit in question.

A first home visit by staff and students to a person who has a psychiatric condition or has experienced a brain injury must always be made by two people. The second person's name and their role need to be declared on the Ethics Application Form.

Ideally, patients/participants should be given the information sheet to discuss with their families at least 48 hours before the first visit.

If you are using computers, or tests requiring a table, you should make sure in advance that, on a home visit, the facilities exist for you to properly do your testing.

Quietness is particularly problematic when testing in the home, and so it is worth discussing whether you will be able to get peace and quiet in a room on your own with the participant for the time you require. Many houses have dogs, doorbells, televisions, and so forth.

In general, patients/participants should not be tested for more than 50 minutes without a break. A maximum of two 50-minute testing sessions in any one day is reasonable, although there are exceptions such as when people have travelled a long distance.

People who have suffered a stroke can often develop pain and discomfort when, for instance, being asked to stare for long periods at a computer screen. They should be frequently monitored for pain and discomfort, and testing stopped if necessary. Test results will be quite invalid if people are in pain or over-fatigued.

There are considerable ethical problems about paying patients for participation in studies. Patients should be given reasonable travel and out-of-pocket expenses if they travel from home (e.g., taxi fares, refreshments).

Where patients/participants are coming into the School, you should make sure that they are able to access the toilet on their own, or if they are not, that someone is accompanying them who can take them to the toilet.

Many patients with brain injury are at increased risk of epilepsy, even though they may not yet have had an epileptic seizure. If your study includes visually-demanding or flickering screens, you should seek consultation and take appropriate advice before running it.

Please complete the following page, sign it and include with your Ethics application. Please **do not** include the entire form - the signed Declaration below will suffice.

SCHOOL OF PSYCHOLOGY, TRINITY COLLEGE DUBLIN
GUIDELINES FOR INTERVIEWING OR TESTING ADULTS

Declaration

I declare that I have read and understood the document '**Guidelines when Interviewing or Testing Adults**'. I agree to abide by these guidelines, and acknowledge that if I breach these guidelines then ethics approval for the study by the TCD School of Psychology Research Ethics Committee will be nullified.

Name (Print):

Signature:

Date:

***Please only return this signed page of this form; do not submit guidelines in entirety.**

Appendix 3: Abbreviations and Terminology

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

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 manual, 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).
- **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. 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.

Appendix 4: 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

Faculty of Health Sciences (FHS)

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