

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

Making An Application

Trinity College Dublin

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1. Introduction

This document is designed to provide guidance when using the Research Ethics Administration Management System (REAMS) to apply for Ethical Approval. Research undertaken by Trinity staff or students, which involves animals, humans, or human data (excluding archival data) requires ethical approval from Trinity. This includes research that has ethical approval from other agencies or institutions, the only exception being projects approved by the [Joint Research Ethics Committee](#) (James & Tallaght Hospitals) (JREC) 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 guidance document is provided to assist the development of robust ethics applications. The following section provides a list of the common abbreviations used throughout this document. There is then an overview of important steps that must be taken when preparing an application for ethical approval. Finally, there are sections that concern the routing of applications to the appropriate reviewing bodies, and the process of review. Based on responses to some of the answers in the ethics application, the REAMS system will automatically direct applications to the appropriate Research Ethics Committee (REC), provide a determination of the level of risk associated with the project, and specify the nature of the review process that is required (i.e., supervisor, expedited, or committee review).

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

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

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

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

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.

Declarations	All student applications require signoff and approval from a supervisor before submission. Any applications not prepared by the nominated PI will also require PI signoff and approval prior to submission
Dependent Sections	Notes
Sampling & Recruitment	Only required if project data are to be collected from primary sources
Data Protection	Required if the Research Data being processed, could directly or indirectly identify a living individual
Animal Research	Required for projects involving invertebrate animals in a laboratory, or data derived from any animals in the wild
Health related Research	Only required if the project is Health Research as defined in the Health Research Regulations
Consent	Required if the project requires consent or assent from participants
Funding	Only required if the project is funded. Funding is usually in the form of a grant.
Human Biological Samples	Only required if the research utilises human biological samples

1.2 Screen shot of Screen & Help Text

Figure 1: Screen shot of screen and help text

Main Project Details

Title of Project *

test feedback

Data Collection Start Date *



Data Collection End Date *



Project End Date *



Does the project involve *

Humans (or their data)

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

- Yes
 No

Only applies to applicants from the School of Law

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

- Yes
 No

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

- Yes
 No

Intentions of the study: Does the project *

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

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

Word limit :100 words

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

Main Project 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. Note if this question is not answered it will be picked up by the system and submission of the application will not be facilitated.

Guidance: Routing

Guidance: Start dates

Guidance: Writing Phase

Guidance: Deception research

Guidance: Intrusive, harmful or can endanger humans

Guidance: Dual purpose

Guidance: Aims and objective (s) and summary

Guidance: Invasive and non-invasive descriptions.

Guidance: Research in a foreign country.

Guidance: Funding

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

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

2. Guidance for completion of the ethics submission

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

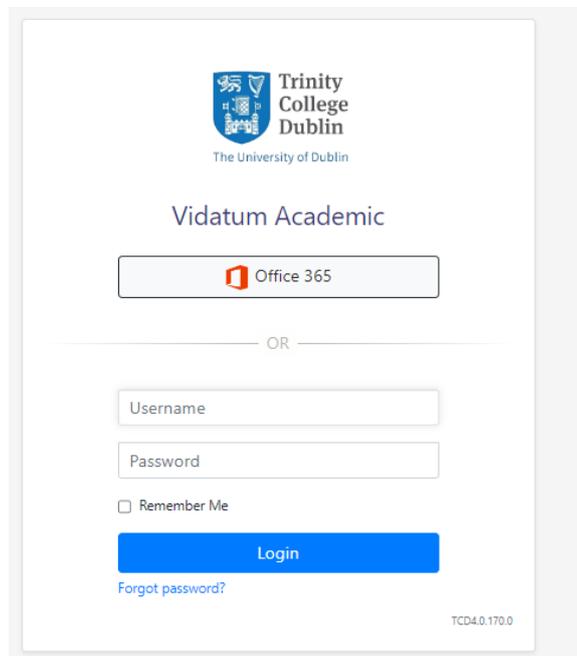
2.1 Introduction to the REAMS system

2.1.1 Sign in and outline of early pages

The web address for the online systems is

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

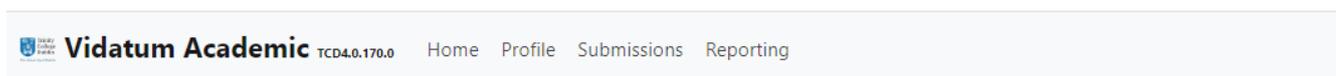
When you open this, the screen below will appear.



Trinity academic staff and students are automatically registered on the system 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:



Click on the submissions tab and the following will appear:

Ethics Review

Search

Awaiting Review

Ethics

New Ethics Application

Search:

REF#	Title	Period	Risk	REC	Submission Date	Status
1758	testing level 1		1	Health Policy		Draft

Click on the New Ethics Application tab and the following screen will appear with a pop-up screen asking you to enter the project title and to select if it is a new application or an amendment:

The next screen shows the opening page of the application and the risk level it is currently classed as.

Test Risk 1

Applicant & Collaborator | Project Details | Attachments

Submit Save Exit

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.

<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>Applicants Details</p> <p>This section is required for all projects</p> <p>Guidance: Role on Project/PI</p> <p>Guidance: Data Protection</p> <p>Guidance: Research Integrity</p>
<p>Is the applicant applying as a member of the staff or as a student?</p> <ul style="list-style-type: none"> • Staff • Student 	<p>Refer to the following documents:</p> <p>Trinity Policy on Good Research Practice</p> <p>Data Protection Training Module</p> <p>Research Integrity in the Open Scholarship Era Training</p>
<p>Staff/ Student number <i>(autofill)</i></p>	
<p>Email address <i>(autofill)</i></p> <p>Applicants need to use their Trinity email address to apply for ethics approval in Trinity</p>	
<p>School / Department <i>(autofill)</i></p> <p>The answer to this question is one of the characteristics used to route the application to the correct REC.</p> <p>Note for applicants who belong to a centre that has a REC, please search for that centre if this is the appropriate REC for your application i.e., Centre of global Health, Centre for Health Policy and Management</p>	
<p>Role on the Project <i>(drop down menu select one)</i></p> <ul style="list-style-type: none"> • Principal Investigator • Non Principal investigator • Other <p>See Guidance: Role in Project to correctly describe your role. If you are not the PI of the project the PI will also be asked to approve the project before submission.</p>	
<p>Primary Employer (if not TCD): <i>(Text field)</i></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) <i>(Text field)</i></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) <i>(autofill)</i></p> <ul style="list-style-type: none"> • PhD • Master by research • Taught Masters 	

<ul style="list-style-type: none"> • UG 	
Part time / full time (student only) (autofill)	
I have read and understood Trinity Policy on Good Research Practice, Yes/No	
<p>I have completed the Integrity module Yes/No/NA</p> <p>Applicants who are undertaking animal studies may choose NA.</p> <p>Staff and non-PhD students may access the Epigeum Research Integrity Training. PhD students (except staff that are conducting PhDs) <u>must</u> complete the Research Integrity in the Open Scholarship Era Training so that they can answer yes to this question and facilitate a completed Research integrity certificate be uploaded. See below for links.</p>	
<p>I have read and completed an up-to-date Data Protection training module in the last 24 months Yes/No</p> <p>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>	

Ethics Review

Search

Awaiting Review

New project Risk 2

Applicant & Collaborator
Project Details
Attachments

← Errors
Save
Exit

Applicant Details

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

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

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

2.2.1 Applicant details

Guidance: 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.

Guidance Research Integrity

When you say yes to this question, you will be required to upload the certificate of completion. With the exception of PhD students who are Trinity members of staff, or students undertaking animal research projects, PhD students **must** complete and upload certification of completion of [Research Integrity in the Open Scholarship Era](#). If you have questions or problems enrolling in the module please contact the module coordinator, Niamh Brennan, (nbrennan@tcd.ie) or email ResearchIntegrity_CA7000@tcd.ie. For non-PhD students and staff, the Epigeum Research Integrity is available, an outline of its content and how to access it is available [here](#).

Guidance Data Protection

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

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](#)

<p>Project Role (drop down menu select one only)</p> <ul style="list-style-type: none"> Trinity Principal Investigator Stakeholder: Academic/ Clinical/Professional/ Industrial Collaborator Primary Supervisor Trinity Co supervisor/s <p>Student applications must include a Primary Trinity Supervisor in this section.</p>	<p>Trinity Collaborators</p> <p>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.</p> <p>Guidance: Trinity Collaborators</p> <p style="text-align: center;">Add Trinity Collaborators</p>
Name	
Email Address	
<p>School or relevant affiliation (Text Field)</p> <p>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.</p>	
Title (Text Field)	

Guidance Trinity Collaborators

Collaborators is the term used here for any member of the research team including supervisors. All must be included in the application and designated as either Trinity collaborators or non-Trinity collaborators. Only Trinity collaborators can access and edit the application online 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 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.

2.2.3 Non-Trinity Collaborators

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

Name	<p>Non Trinity Collaborators</p> <p>Collaborators are members of the research team. Non-Trinity collaborators cannot access or edit this application online.</p> <p>Guidance: Non Trinity Collaborators</p> <p>Guidance: Participant collaborator and participatory research</p> <p>Add non-Trinity Collaborators</p>
Email Address	
Project Role (drop down menu 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>) 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) 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.	

Guidance: Non-Trinity Collaborators

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

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

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

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

Projects that are **solely** exploratory discussions to develop a research question with an advisory group/governance group/ persons or post project discussions regarding the marketing or commercialisation of the outputs of the research usually

do not require ethical approval. Such explorations may however give rise to legal and reputational considerations that should be addressed elsewhere. An as example, the collection of contact details may have legal implications relating to data protection. If all processes are not sufficiently transparent reputational considerations may emerge. This may occur, for example, if the persons engaged are not made aware that they can withdraw from the process at any time.

Guidance: Participant Collaborator/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, It other sections/ tabs for completion (e.g., consent, animal research, data protection. This information will also be used to determine the assessed risk level of the project, and therefore whether the project is routed to Level 1, Level 2 or Level 3 and, within Level 2 and 3, whether the project will be sent for expedited review or committee review.

2.3.1 Main project details

This subsection appears for all projects including animal projects

<p>Title of project (Text field)</p> <p>This is imported from previous insertion into the system, if it needs to be changed this is the place to change it</p>	<p>Main Project Details</p> <p>This section is required in all projects. Read the guidance document carefully when completing this section.</p> <p>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.</p> <p>Guidance: Start dates</p> <p>Guidance: Writing Phase</p>
<p>Data collection start date (calendar presented)</p>	
<p>Data collection end date (calendar presented)</p>	
<p>Project end date (calendar presented)</p>	
<p>Does the project involve (drop down list)</p> <ul style="list-style-type: none"> • Humans (or their data) • Animals 	

<p>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.</p> <p>If “humans” (or their data) is selected the following two animal question will not appear and the rest of this section will.</p>	<p>Guidance: Deception Research</p> <p>Guidance: Intrusive, harmful or may endanger humans</p> <p>Guidance: Dual purpose research that could be misdirected to do harm</p> <p>Guidance: Aims and objective (s) and summary</p> <p>Guidance: Research in a foreign country</p> <p>https://www.tcd.ie/estatesandfacilities/shared-admin-and-support/insurance/</p> <p>https://www.dfa.ie/travel/travel-advice/</p> <p>Guidance: Invasive and non-invasive descriptions.</p> <p>Guidance: Funding</p> <p>Guidance: AREC/ animal research projects: please refer to the guidance to obtain further information on the projects that fit under these categories</p> <p>Guidance: Aggregate Data</p> <p>Guidance: Features of Data that Fall Outside the Remit of the GDPR</p>
<p>Does the project animal involve - (<i>Drop down menu, select one only</i>)</p> <ol style="list-style-type: none"> 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 	
<p>The following question will appear if option 1 above is selected</p> <p>Is the AREC project a first application or an amendment?</p> <ul style="list-style-type: none"> • First application • Amendment • Not applicable 	
<p>Is the research WHOLLY (i) an analysis of statutes/legal provisions AND/OR (ii) legal judgments/cases which have been made public by a judicial process? Yes /No</p> <p>This question applies to applicants from the School of Law only, all other applicants should answer no.</p> <p>Answering yes to this question facilitates automatic routing to Level 1.</p>	
<p>Trinity Researchers will have access only to aggregate data or data that otherwise fall outside of the remit of the GDPR.</p> <p>Yes / No</p> <p>Answering yes to this question facilitates automatic routing to Level 1.</p>	
<p>Could the research have detrimental legal, economic or social consequences for either the participants or their establishments. Yes/ No</p> <p>Answering yes to this question facilitates automatic routing to Level 3.</p>	

Intentions of study: Does the project: *(Multiselect available, you can choose more than one if applicable)*

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

Unless the item “none of the above” is selected this question will route this project to Level 3 committees

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

Word limit :100 words

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

Identify all countries where data is collected or processed *(Drop down menu)*

If some or all of your research is taking place in a foreign country, please be aware that you are not insured to travel to countries that are on the Department of foreign affairs travel list.

For convenience Ireland is on the top of the list, after that they are in alphabetical order so just start writing the name of the country and it will automatically come up.

Does the project involve: *(select one only)*

1. Human participants and /or their data and no biological samples
2. Human biological samples not from patients taken in a non-invasive manner
3. Human biological samples from patients
4. Human biological samples taken in an invasive manner
5. Human biological samples of any size or type that could have an impact upon future treatment (e.g., human DNA sequencing)

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

Answers 3-5 will facilitate routing to Level 3.	
Answers 2-5 will facilitate the generation of the Human Biological Sample tab	
Is the project funded? Yes/No	
This question facilitates generation of a funding tab	

Guidance: Aggregate Data

Aggregate data are a form of data used for statistical purposes. Recital 162 of the GDPR states, “Statistical purposes mean any operation of collection and the processing of personal data necessary for statistical surveys or for the production of statistical results. Those statistical results may further be used for different purposes, including a scientific research purpose”. Accordingly, these purposes imply that, “the result of processing for statistical purposes is not personal data, but aggregate data, and that this result or the personal data are not used in support of measures or decisions regarding any particular natural person” (GDPR, Recital 162).

In this context, when a researcher utilises aggregate data, they should have no means of accessing the raw (person-specific) information. Rather, the aggregate data are made available to the researcher in terms of totals or summaries.

It should however be noted that, when the appropriate analysis methods are used, aggregate data may have the potential to reveal personal information. Aggregation may protect privacy however it cannot be guaranteed that it will always do so. Ideally, aggregate data should be derived from data that are anonymous at source.

Guidance: Features of Data that Fall Outside the Remit of the GDPR

Information “which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable”, is outside the remit of the GDPR. It should be noted that, within the European Economic Area (EEA), if it is the case that there exists a key anywhere, such that the data subject is potentially identifiable, the the data cannot be considered anonymous under the law. In other words, the mere fact that an individual data processor does not have access to the key, does not alter the designation of the data, or exclude the processing of the data from the scope of the GDPR. These considerations notwithstanding, it may nonetheless be the case that a project that involves the processing of data that has been de-identified may, in some circumstances, be deemed to “low risk” – from a Data Protection impact perspective. For example, publicly available information that is non confidential, may be deemed “low risk”. In addition, the GDPR generally does not apply to deceased persons (Recital 160).

Guidance: Start Dates

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

Guidance: Writing Phase

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

Guidance Deception Research

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

Guidance: Potentially Intrusive or Harmful

While all research is intrusive to some degree, intrusive topics are likely to cause risk or discomfort greater than that usually encountered during daily life. The inclusion of such topics therefore increases the risk to participants. Examples of topics that would be considered as intrusive include, but are not limited to, abortion, abuse, animal abuse, bankruptcy, bullying, child abuse, gun control, self-harm, trauma, whistleblowing. Projects that explore intrusive topics will be routed to Level 3 RECs.

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

Guidance: Dual Purpose

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

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

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

Guidance: Research in a Foreign Country

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

Guidance: Aims and Objectives

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

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

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

Guidance: Fundings

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

Guidance: Invasive and Non-invasive

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

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

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

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 and if student projects will be reviewed by the supervisor
 - a. Sampling sustainable numbers from populations of invertebrate subjects (other than cephalopods), irrespective of subsequent processes.
 - b. Observations of vertebrate subjects left undisturbed in their natural environment.
 - c. Non-destructive measurement or observation of wild / managed environments
 - d. Translocations of small numbers (compared to local population sizes) of individuals of a native species between sites all within the local area.
3. **Category 1: Low risk wildlife and ecology projects.** These projects will be routed to the School of Natural Sciences REC as they are low risk, they will take the expedited review route.
 - a. Translocations of large numbers of individuals of a native species or from further than they can travel naturally, or of non-native species.
 - b. Capture and removal of wild vertebrates, under licence from the relevant specialist body, or those deemed vermin.
 - c. Brief (less than a 2 hours) capture of small numbers (as a proportion of the local population) of wild vertebrates and return to their original site of capture.
4. **Category 2: Low risk wildlife and ecology projects.** These projects will be routed to the School of Natural Sciences REC as they are slightly higher risk than Category 1 they will take the committee review route.
 - a. Capture and removal of wild vertebrates without licence from the relevant specialist body.

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

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:

- "Is the research WHOLLY (i) an analysis of statutes/legal provisions AND/OR (ii) legal judgments/cases which have been made public by a judicial process?"
- ‘Trinity Researchers will have access ONLY to aggregate data or data that otherwise fall outside of the remit of the GDPR’.

<p>Is your study a mixed methods study?</p>	<p>Details on Human Participants and their Data</p> <p>Guidance: Mixed methods</p> <p>Guidance: Data source</p> <p>Guidance: Publicly available data</p> <p>Research data are the data required to meet the aims and objectives of the study.</p> <p>If primary sources are selected a draft participant information leaflet will be generated for development.</p> <p>Guidance: Secondary analysis</p> <p>Guidance: Informed Consent</p> <p>Guidance: Proxy</p> <p>Guidance: Assent</p> <p>Guidance: Explicit Consent</p> <p>Link to Explicit Consent templates</p> <p>Guidance: Health Research</p> <p>If paying participants refer Gift Voucher Policy.</p> <p>Guidance: Personal data</p> <p>Guidance: Publicly available data</p> <p>Guidance: Directly and indirectly identifiable data</p> <p>Guidance: Data retention</p> <p>Guidance Risk of Vulnerability</p> <p>Guidance: Healthy participants in a health trial</p> <p>Guidance: Dependant relationship</p> <p>Policy on Good Research Practice</p>
<p>Does the project use data from: <i>(select one only)</i></p> <ul style="list-style-type: none"> • Primary sources only • Both primary sources and secondary sources • Secondary sources only <p><i>The following question will only appear if the answer secondary data is being collected</i></p>	
<p>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</p> <p>If no, provide further information</p> <p><i>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.</i></p>	
<p>Will payment be made to research participants?</p> <ul style="list-style-type: none"> • YES – standard gratuity with or without expenses • YES - receives a gratuity in excess of standard with or without expenses • No <p>If yes, receives a gratuity in excess an additional box will be inserted:</p> <p>Provide further information</p>	
<p>Is the project Health Research as defined by the health regulations? Yes/No</p> <p>If answer to health is yes generate next question</p>	
<p>Does the project require a consent declaration form as defined by the Health Research Regulations 2018 and amendment 2021? Yes /No</p>	
<p>Could any of the research data directly identify any participant? Yes/No</p>	

<p>Note this question only applies to research data see question below for other project information that has personal information</p> <p>Answer yes to having directly or indirectly identifiable data the project cannot be routed to Level 1 and a data protection section will be generated</p>	<p>Staff and students of Trinity as participants</p> <p>Guidance: JREC</p>
<p>Could any of the research data directly identify any participant?</p> <p>Note this question only applies to research data see question below for other project information that has personal information.</p> <p>Answer yes to having directly or indirectly identifiable data the project cannot be routed to Level 1 and a data protection section will be generated.</p>	
<p>Do you process personal data for study administration purposes? e.g., contacting individuals Yes/ No</p> <p>If answer is yes an additional text box will appear:</p> <p>Outline how you will store the information, keep it confidential, and destroy it in line with the data retention policy.</p> <p>Answer yes to this question and the project cannot be routed to Level 1.</p>	
<p>Which of the following best describes the general characteristics of the target population? (<i>Multiselect you may choose more than one</i>)</p> <ol style="list-style-type: none"> Adults currently not at risk of vulnerability Adults at risk of vulnerability Children (<18 years) Participants with a dependant relationship with the researcher Staff of Trinity Students of Trinity <p>If answer is b-d the project will be routed to Level 3 ethics committees. If E & F are selected this will add the required permissions as a required attachment.</p>	
<p>This question will only appear if your answer to is your research health research is yes.</p> <p>Do any of the following describe the characteristics of the target population? (<i>Select only one</i>)</p> <ul style="list-style-type: none"> ▪ 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 <p>If other is selected an additional text box will appear:</p> <p>Please Describe</p>	

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

Guidance: 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.

Guidance: Mixed Methods

There are two types of mixed method 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 mixed methods will be requested in two separate phases. As a result, the question on mixed methods 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)

Guidance: Data Source

Definition of research data:

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

In the present context, research data is the data required to meet the aims and objectives of the Project. Research data may include Personal Data (for further information please consult Data Protection Key Words). Administrative data that is used to support the Project, such as participant contact details, may also contain Personal Data.

Research data is generally categorised in two ways: Primary Data and Secondary Data:

Primary Data is data collected directly from participants by the researcher or by a member of the research team, specifically for the purposes of the Project. Means of data collection might include, for example, the use of a questionnaire or questionnaires, an interview, a photograph, an observation or an audio or video recording.

Secondary Data is data that has been collected for a different purpose, and in most cases by a different person or persons, which is re-used for the Project. Common examples of secondary data are students' exam results, patient data or professional profile data. Some projects use both primary and secondary data. For example; research study participants are interviewed and information concerning those participants is also extracted from their public profiles and privately-held records.

Both Primary Data and Secondary Data may contain Personal Data and would therefore be subject to data protection law.

Projects that use Secondary Data may require ethical approval, even if it is the case that the Secondary Data is publicly available.

Guidance: Secondary Analysis

11th October 2022 - not addressing this at this stage. Discuss further at 11th October meeting.

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

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

The reuse of data has many advantages, and many research funders now commonly require data to be archived and made publicly accessible. To be suitable, and subsequently made available for secondary analysis therefore, data need to be collected, stored, and accessed in a manner that is ethically and lawfully appropriate.

The ethical risk associated with the secondary use and/or analysis of data ranges from low risk in projects which use anonymous, and/or quantitative data that concerns non-intrusive topics, to high-risk projects such as qualitative studies on intrusive topics or projects which use personal or sensitive data. Depending on the nature of the original ethical approval, and the consent given by the (human) participants, projects that will use data for a purpose other than originally specified, may require subsequent ethical approval. Consult your supervisor and/ or local research ethics committee to discuss any such considerations before making an application.

Guidance: Publicly Available Data

11th October 2022 - not addressing this at this stage. Discuss further at 11th October meeting.

More than ever within a digital and Open Research Environment (section 5.8 Data sharing [Policy for Good Research Practice](#)), researchers can access data collected by others. Overtly public data can be obtained directly, without permission or licence. Such data may include information concerning public figures, derived from blogs or other digital sources. As such data will usually have been collected for a different purpose, their use may constitute secondary analysis.

Researchers should not assume that they can or should undertake analysis of such data, as they are not the owner of the data and may not have permission for the data to be used in research. While the risk associated with this type of research is likely to be low, it must nonetheless be assessed, and ethical approval may be required. Relevant considerations are the category of researcher (student or staff) and the level of risk. For example, the research may relate to an intrusive topic or concern vulnerable persons (see Secondary analysis).

Guidance: Directly or Indirectly Identifiable Data:

11th October 2022 - not addressing this at this stage. Discuss further at 11th October meeting.

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

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

Guidance: 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/>.

Guidance: Explicit Consent

If your Project is “health research”, as defined in the [Health Research Regulations 2018](#) (as amended) (“HRR”), 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](#).

Guidance: 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](#).

Guidance: 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.

Guidance: 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.**

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

Personal Data and Data Retention

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](#) and [Data Protection Handbook](#).

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).

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

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 Project 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 information is available from Trinity College [IT Services](#).

Further Guidance:

1. Data Protection Commission Guidance on the Principles of GDPR - available [here](#).
2. For guidance on data management. See CESSDA Data Management Expert Guide - available [here](#).
3. Data Protection Commission Guidance on Anonymisation and Pseudonymisation- available [here](#).
4. Trinity College Data Storage and Sharing Overview - 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.

Guidance: Vulnerability

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

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

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

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

Guidance: Dependant Relationship

Examples of dependant relationships include a carer/ clinician and the person they care for, an educator and a pupil, a line manager and an employee. These relationships are more likely to be open to coercion, in that an employee for

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

Guidance: Healthy Participants in a Health Trial

If you are conducting Health Research - see [Guidance: Health Research](#) - the Health Research Regulations 2018 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.

2.3.3 Research Sources and Sites

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

New Ethics Site ✕

Name data collectionsite/source *

Does this site / source / study 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 from this site

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

Was a DPIA required at this site/ source, if yes please attach the completed DPIA *

No
 Yes

[Submit](#)

Research Sites

Enter the information requested for each site. To complete your application you must upload permission documentation, access site ethics for each site named and if applicable a DPIA.

[Guidance: Site Ethics](#)

[Link to Data Protection Impact Assessment \(DPIA\)](#)

[Add new site](#)

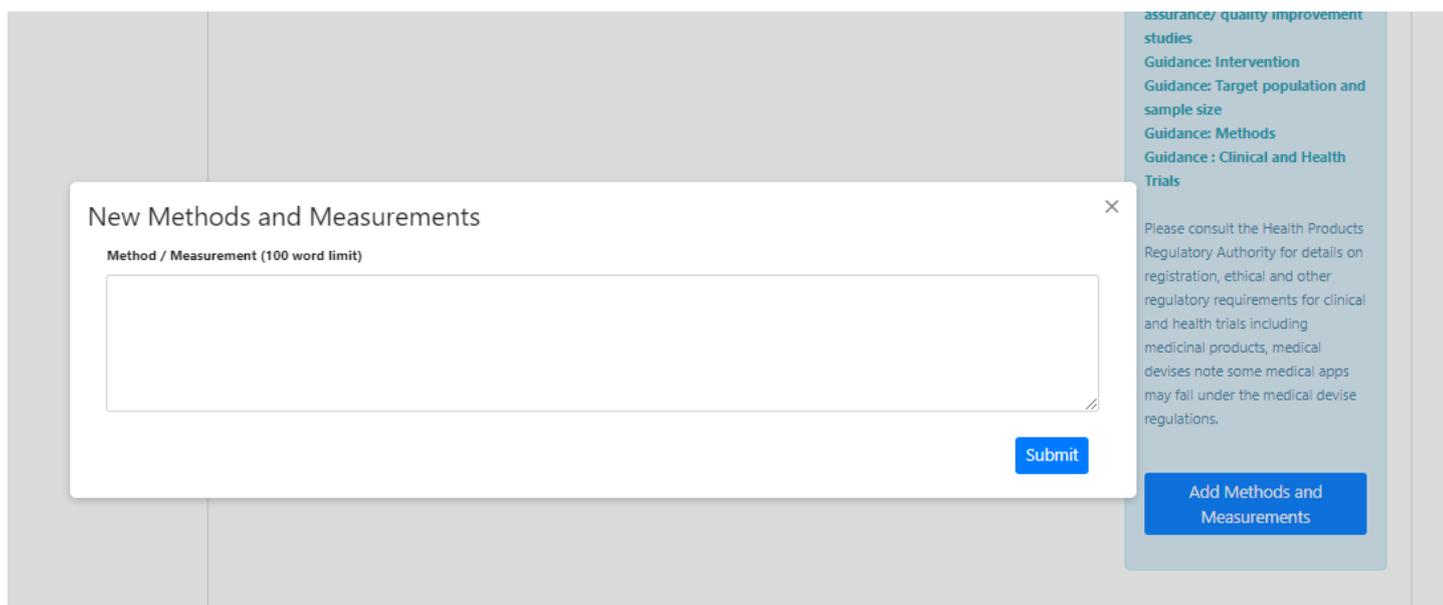
<p>Name data collection site /source</p>	<p>Research Sites and data sources</p> <p>Enter the information requested for each site. To complete your application, you must upload permission documentation, access site ethics for each site named and if applicable a DPIA.</p> <p>Guidance: Site ethics</p> <p>Guidance: Low risk methods</p> <p>Data Protection Impact Assessment</p> <p style="text-align: center;">Add new site / source</p>
<p>Does this site / source/ study require licence to use, access permission and /or ethics approval? <i>(Select one)</i></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>If you project requires both ethics and access, please merge these documents in the one attachment.</p>	
<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.</p>	
<p>Was a DPIA required at this site/ source? Yes/No If yes, please attach the agreed/ approved external DPIA</p>	

Guidance: Site Ethics

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

2.3.4 Outline of Project Methods

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



<p>Outline the Data Collection methods</p> <p>For each method employed add a methods and/or measurements i.e., survey, focus group questions, blood tests</p> <p>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.</p>	<p>Methods and measurements</p> <p><u>Outline of Project Methods</u> Add methods and Measurements Create individual entries for each instrument, sample, measurement and test you will use. When describing the instrument of data collection, indicate if the instrument/s is currently usual practice or how it differs from usual practice (if applicable) or if completely new to the cohort being researched. i.e., student survey utilising Trinity annual student survey form with additional section of questions to evaluate new changes in practice. <u>Interventions:</u> 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.</p>
<p>Does your project use any of the following methods exclusively? (<i>Select one only</i>)</p> <ol style="list-style-type: none"> 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 	

<p>5. Information, documents or data which are in the public domain</p> <p>6. A data source not publicly available but which you have permission to use</p> <p>7. No</p> <p>If 1-4 selected this is a criteria that is needed for routing to Level 1 and is a criteria for expedited review at Level 2 or 3</p>	<p>Guidance: Low risk methods</p> <p>Guidance: Audits of standard practice and /or quality assurance/ quality improvement studies</p> <p>Guidance: Intervention</p> <p>Guidance: Target Population and Sample Size</p>
<p>Does the project include an intervention? Yes/No</p> <p>The following two questions will appear if you answer to the above intervention question is yes.</p>	<p>Guidance: Methods</p>
<p>Please select which of the following best describes the intervention (<i>select one only</i>)</p> <p>1) Health non trial (including, psychology, social care including educational intervention)</p> <p>2) Health trial (including, psychology, social care, including educational intervention)</p> <p>3) Educational</p> <p>4) Other</p>	<p>Guidance for Clinical research / Clinical trials should consult the Health Products Regulatory Authority for details on registration, ethical and other regulatory requirements for clinical and health trials including medicinal products, medical devices note some medical apps may fall under the medical device regulations.</p>
<p>Outline the intervention/s (<i>Text field</i>)</p>	
<p>What is the approximate size of the target population? (<i>Number</i>)</p>	
<p>What is the proposed sample size -how many participants are involved in the study? (<i>Number</i>)</p>	
<p>Justification for the sample size (<i>Text field</i>)</p>	
<p>Outline the method of analysis (Word limit :100 words) (<i>Text field</i>)</p>	

Guidance: Low Risk Methods

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

Guidance: Audits of Standard Practice/ 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, and when reviewed at Level 2 or Level 3 the application may be considered for expedited review.

Guidance: Methods

Two questions refer to the methods used. In the first of these, you are required to outline the data collection methods e.g., interview, survey, questionnaire, blood samples etc. In the second question you will be asked to name any specific instruments that will be used. The responses may include the names of specific questionnaires, a data extraction instrument, interview/ focus group guide, method of blood sampling, measurement tool, results of tests etc. Each of the items that is listed in response to this question will be recorded by the system. An attachment that corresponds to each instrument must then be uploaded. 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.

Guidance: Intervention

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

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

Guidance: Target Population 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.

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

2.4 Sampling and recruitment

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

Guidance: Sampling method

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

Guidance: Time commitment

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

Guidance: Gate keeper

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

Guidance: Recruitment

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

2.5 Animal Research

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

<p>What setting/s will be used for data collection (<i>Multi selection select all that apply</i>)</p> <ul style="list-style-type: none">1) Laboratory2) In the wild3) Other	<p>Animal Research</p> <p>The Section is required because your project involves animals.</p>
<p>Describe the project including the taxa and species used and the sample size. (<i>Text field</i>)</p>	
<p>Outline the potential benefits likely to derive from the project. (<i>Text field</i>)</p>	
<p>Describe the impact of the research on the subjects and their environment. Describe the mitigation of these risks. (<i>Text field</i>)</p>	
<p>Describe any risk to the researcher of carrying out the research. Describe the mitigation of these risks. (<i>Text field</i>)</p>	
<p>Is this work covered by any externally held licence? Yes /No</p> <p>If the answer is Yes, this will add Licence to the attachments required for submission.</p>	

2.6 Health Research

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

<p>Please indicate which of the following applies to your health research project:</p> <ul style="list-style-type: none"> • 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 <p>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.</p> <p>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.</p>	<p>This section is required because your research meets the definition of the Health Research Regulations 2018. Health research generally requires explicit consent unless the conditions for an exception are met.</p> <p>Guidance: Health Research</p> <p>Guidance: Consent</p> <p>Guidance: Explicit Consent</p> <p>Guidance: PI and insurance and Consent declaration</p> <p>Health Research Regulations 2018 and Health Research Regulations amendments 2021</p>
<p>Is the PI a medical doctor / dentist covered by the state claims agency (SCA) Clinical Indemnity Scheme (CIS) for research conducted within a designated state authority (HSE hospital or Service Provider)? Yes/ No</p> <p>Only required is an intervention is part of the project protocol.</p>	
<p>Will the project involve the administration of any substances or require participants to refrain from taking any substance? Yes/ No</p> <p>If yes please detail, substance, amount, desired effect, possible side effects, measures for minimising risks.</p>	
<p>Will there be ongoing clinical supervision of the participants by a duly insured clinical practitioner during the project? Yes/ No</p>	
<p>Will the research participants' General Practitioner be informed that they are taking part in the project? Yes/ No</p>	
<p>Will permission be sought from the research participants to disclose information (for example, information about adverse outcomes) to their GP? Yes/ No</p>	

With regard the question "Will the research participants' General Practitioner be informed that they are taking part in the project" if the project gives the participant the choice to yes or no to the GP being informed, answer Yes to this question.

Guidance: 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 doctor / dentist 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: *Minor revision approval in principle awaiting Consent Declaration*. 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

How will consent be obtained and by whom? <i>(Text field)</i>	<p>HELP TEXT:</p> <p>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.</p> <p>Guidance: Consent</p> <p>Guidance: Risk of vulnerability</p> <p>Guidance: Garda vetting clearance</p> <p>Guidance: Time interval</p> <p>Guidance: Participants withdrawing from project</p>
Do your participants require support to give consent? Yes/No If yes, a provide further information will appear See Risk of Vulnerability for more information on support needs	
Do you require assent from participants e.g., because of their vulnerability? Yes/No If yes, a provide further information will appear.	
How will assent be obtained and by whom? <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 	
If less than 7 days a provide further information box will appear.	
Describe how you will inform participants about the use of their personal data This answer will be inserted into the draft PIL for you to adapt.	
Describe how participants can withdraw their consent and/ or their data This answer will be inserted into the draft PIL for you to adapt.	

Guidance: Garda vetting

It is a legal requirement that researchers who undertake research 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.

Guidance: Time interval

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

Guidance: Participants Withdrawing from Project

Personal data in the form of contact details and consent can be withdrawn at any time at the participant's request. Project data, 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 the column on the left will have a button for add risk.

<p>What setting/s will be used for data collection (<i>choose all that apply</i>)</p> <ul style="list-style-type: none"> • Place of convenience for participant • Participant's place of work • Participant's home • Classroom • Hospital/clinic • Laboratory • In a foreign Country • Online • Other 	<p>Risk to Researcher</p> <p>This section is mandatory for all projects.</p> <p>Click on the add button below for each researcher risk.</p> <p><u>Guidance: Risk, benefit, harm to researcher, participant, environment and society.</u></p> <p><u>Guidance: Lone worker</u></p>
<p>If other elaborate</p>	

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

Researcher Risk
<p>Identify the risk from the list below</p> <ul style="list-style-type: none"> • 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 <p>If other elaborate</p> <p>If none if selected the following additional question will be blocked out and the box is ready to press submission</p>
<p>Estimate the Impact:</p> <ul style="list-style-type: none"> • Low • Medium • High
<p>Estimate the Probability/ likelihood:</p> <ul style="list-style-type: none"> • Low

- Medium
- High

Detail the Mitigation measures (*Text field*)

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

This question is for School of Psychology only

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

Guidance: Risk benefit harm to researcher, environment and society

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

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

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

One way to do this is to consider whether the data collection phase of your project, or your results of your study, *could* have a negative impact. Here are some examples. Do you have permission to reveal the site name? Are the data collected and published in a manner such that the identities of individuals involved cannot be revealed 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.

Guidance: Lone worker

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

2.8.2 Risk, harm to site, environment, or society

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

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

2.8.3 Risk to participant

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

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

Add Risk
<p>Identify the risk from the list below</p> <ul style="list-style-type: none">• 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 <p>If other elaborate</p> <p>If none if selected the following additional question will be blocked out and the box is ready to press submission.</p>
<p>Estimate the Impact:</p> <ul style="list-style-type: none">• Low• Medium• High
<p>Estimate the Probability/ likelihood:</p> <ul style="list-style-type: none">• Low• Medium• High
<p>Detail the Mitigation measures <i>(Text field)</i></p>

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.	<u>Guidance benefits</u>
Outline any direct benefits of participation to research participants	

Guidance: Participant risk

All projects have some risk and impose some burden upon participants. In assessing the potential risk to participants, consider the worst-case scenario. If your previous experience is not sufficient to gauge the risks that may arise, consult with your supervisory team / colleagues, or with recognised experts in the field. All risks must be specifically identified and stated. On balance the benefit of taking part in a project (which may not be derived directly by the participant) should always outweigh the risks. In most studies inconvenience (i.e., the time it takes to be part of the study), and loss of privacy (i.e., that participants reveal some personal data to the researchers), are the most common risks. These may have relatively low impact, but still need to be minimised. Other projects, particularly intervention studies, may have higher impact, which will 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.

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

Guidance: Revealing information/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.”*

Guidance Benefits

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

2.8.5 Conflict of Interest

<p>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</p> <p>If yes: Give details of the Conflict of Interest and what mitigation measures are in place</p>	<p>Conflicts of Interest</p> <p>Conflicts of Interest arising from project funding will be dealt with separately and should not be entered here.</p> <p>Guidance: Conflict of interest</p>
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Guidance: Conflict of Interest

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

2.9 Funding

<p>Insert RPAMS number if applicable and available</p>	<p>Funding</p> <p>This section is required because you have indicated that your project is funded.</p> <p>Guidance RPAMS Number and Sources of funding</p> <p>Guidance: Conflict of Interest re Funding</p> <p>Guidance: Disclosure re Funding</p> <p>Declaration of Interest Form</p> <p>Guidance: Commercialisation</p>
<p>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. <i>(Text field)</i></p>	
<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>Follow up question if answer is yes: 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>If yes: Give details of the Conflict of Interest and what mitigation measures are in place</p>	

It there likely to be possible conflict of interest between the funders of the project and the aims and results of the project.	
---	--

Yes/No

If yes: Give details of the Conflict of Interest and what mitigation measures are in place. *(Text field)*

Guidance: RPAMS no. and sources of funding

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

If you have funding administered by Trinity 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.

Guidance: Conflict of Interest re Funding

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 at:

https://www.tcd.ie/about/policies/Good_Research_Practice_June2021.pdf

Guidance: Disclosure re Funding

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:

https://www.tcd.ie/about/policies/Good_Research_Practice_June2021.pdf

Guidance: 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 at

<https://www.tcd.ie/about/policies/assets/pdf/Intellectual-Property-Policy-2018.pdf>

2.10 Human Biological Samples

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

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

Guidance: Biological samples

Careful consideration and respect are required in the gathering, storage and destruction of biological samples of all types 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

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

Please note that the Data Protection Office approval is now integrated in the REAMs platform and there is now no direct communication to the DPO on the data protection elements of ethical applications. The DPO will review the application within the REAMs platform and you will be notified of data protection feedback from the DPO via the REAMs platform.

2.11.1 Opening questions

This section is required because your Research Data contains information that could directly or indirectly identify a participant

<p>Have all Trinity researchers (staff and students) in this project completed the College Data protection GDPR training module? <i>Yes /No</i></p> <p>Review guidance before answering</p>	<p>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.</p>
<p>Are all Trinity Staff and Trinity Students in this project familiar with the Trinity College Personal Data Breach Procedural Guidelines?</p> <p>Application cannot proceed unless the answer to the question is 'Yes'</p>	<p><u>Guidance: Data protection office: section opening questions</u></p>

2.11.2 Data Protection Assessment

<p>What is Trinity's role in the project? <i>(Drop down menu)</i></p> <ul style="list-style-type: none"> • Controller • Joint controller • Processor 	<p><u>Guidance: Data Protection Office: Data Protection Assessment</u></p>
<p>How many participants' personal data are being processed in this project? <i>(Drop down menu)</i></p> <ul style="list-style-type: none"> • ≥30 • <30 	
<p>List all types of personal data (including any special category or sensitive personal data) that you will process during the lifecycle of the project. <i>(Text field)</i></p>	
<p>Does the project involve processing of special category data or data relating to criminal convictions and/or offences (sensitive personal data)? <i>Yes / No</i></p>	
<p>Is the personal data shared outside the research team with any other units within Trinity College? <i>Yes / No</i></p>	
<p>Name these units <i>(Text Field)</i> Detail what personal data will be shared with them and why</p>	
<p>Is the personal data shared with any third party outside of Trinity? <i>Yes /No</i></p>	
<p>Provide names of these organisations and detail what personal data will be shared with them and why. <i>(Text Field)</i></p>	
<p>Describe what IT due diligence you intend to carry out or have carried out on these organisations <i>(Text Field)</i></p>	
<p>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</p>	
<p>Are the personal data transferred outside of the UK &EEA? <i>Yes/No</i> If yes, you must contact the Data Protection Office.</p>	
<p>Detail how long the personal data will be retained for in an identifiable or coded format. <i>(Text field)</i></p>	

2.11.3 Data Protection Risk Assessment (DPRA)

Does the project involve matching or combining datasets?	Guidance Data Protection Office: Data Protection Risk Assessment (DPRA)
Are the topics explored in the project intrusive or sensitive in nature?	
Does the project use personal data on a large scale (NB Large scale does not necessarily equate to large number)	
Does the project involve the processing of personal data relating to participants who belong to a vulnerable segment of the population?	
Are the participants individuals with a rare condition or disease?	
Does the project involve the use of new technologies or organisational solutions?	
Does the project involve processing of special category data or data relating to criminal convictions and/or offences (sensitive personal data).	
Does the project involve systematic monitoring, tracking or observing individuals' location or behaviour?	
Could the project result in automated decisions being made, including profiling or actions being taken against individual(s), in ways that could have a significant impact on them?	
Does the project involve the profiling evaluation or scoring, including profiling and predicting, of individuals to make generalisations about an individual that could lead to significant decisions being made that could directly affect the individual?	
Could the project prevent individuals from exercising a right, using a service, or fulfilling a contract?	

2.11.4 Data Protection Impact Assessment (DPIA)

Why is the processing of personal data (i.e., data relating to an identified or identifiable living individual) necessary for the project? (<i>Text Field</i>)	Guidance: Data Protection Office: Data Protection Impact Assessment (DPIA)
--	--

How often (at what frequency) will you be collecting data from individual participants? *(Field Text)*

Indicate which Article 6 lawful basis you are relying on for the use of personal data.

(Drop down menu select one)

- Consent
- Performance of a contract
- Legal obligation
- Public interest or exercise of official authority
- Vital interest of data subjects
- Legitimate interest

A legal basis is required to process personal data – review Guidance before answering

Are you capturing explicit consent for the use of special category data? Yes / No

Please list which Article 9 condition(s) you are relying on for the use of special category personal data - select all that apply.

- Employment/Department of Social protection (DSP) Rights
- Vital interests of the data subject or another person carried out internally by a not for profit organisation
- Not-for-profit body with a political, philosophical, religious or trade union aim
- Information that has already been made public by the data subject
- Necessary for the Establishment, Exercise or Defence of Legal Claims
- Necessary for a substantial public interest
- Preventive or occupational medicine
- Necessary For Reasons of Public Interest in the area of Public Health
- Archiving purposes in the public interest/scientific or Historical research purposes/statistical purposes

Describe plans that are in place for responding to any requests from individuals in relation to their data protection rights. *(Text Field)*

<p>How will the data be kept accurate and up to date and be of sufficient quality for the research project? <i>(Text field)</i></p>	
<p>Purpose Limitation - Is the processing for the intended purpose only, or is there possibility that additional purposes may be added at a later date? <i>(Text field)</i></p>	
<p>Data Minimisation - Have you ensured that you will only collect the minimum data that you need or that is necessary for the activity? Provide details. <i>(Text field)</i></p>	
<p>Who is authorised to access the data and describe how this access is controlled <i>(Text field)</i></p>	
<p>I confirm that all accounts created on relevant software systems have passwords configured which comply with the Trinity Password Policy: i.e., Minimum of 8 characters, mixture of upper lowercase and special characters. It is a requirement that the answer to this is 'Yes'.</p>	
<p>Are you using multi-factor authentication to access all systems you use for the project data? DPO to be contacted if answer is 'No'.</p>	
<p>Detail how and when you will code / pseudonymise personal data / information you are using for the project (if applicable). Detail how and when the personal data / information will be archived / anonymised / deleted / destroyed (as applicable).</p>	

2.11.5 Processing risk

All projects that have personal data in their research will be presented with this section, there the applicant will assess each risk and describe how it will be mitigated for. Each risk is added separately by clicking on the " add processing risk button on the left hand columns indicated below

Processing Risk

No data available in this section.

Processing Risk
 Processing means any activity involving personal data See Guidance: Data Protection

Add Processing Risk

The following table to be completed will then appear

<p>List the processing risks of any kind</p> <p><i>For each risk listed the following three questions will be asked</i></p>	
<p>Likelihood (<i>drop down menu</i>)</p> <ul style="list-style-type: none"> • Low • Medium • High 	<p>Guidance: Data Protection Office: Data Protection Processing Risk</p>
<p>Severity/impact (<i>drop down menu</i>)</p> <ul style="list-style-type: none"> • Low • Medium • High 	
<p>Solutions/mitigation actions (<i>Text Field</i>)</p>	

2.11.6 Closing section

<p>Include any additional information in respect of the study which may be relevant.</p>	<p>Provide details that you believe to be relevant, but which have not been asked in this section.</p>
--	--

2.12 Attachments

2.12.1 Required Attachments

As you work your way through the application form, and as indicated earlier, the answers given to certain questions will determine whether generic or specific attachments (where a site, location or person is named within brackets) are required. An attachment list will be generated accordingly. It is necessary that all the attachments included in this list are uploaded before submission can occur.

Ethics Review Attachments

The following attachments are required before submission

- Data Protection Training certificate
- Consent Form
- Recruitment Documentation
- Garda Vetting Clearance
- Participant Information Leaflet (PIL)
- Draft Consent Declaration
- Guidelines when interviewing or testing adults / children
- Method / Measurement (For Measurement: focus group of approx. 50 mins)
- Method / Measurement (For Measurement: test 2)
- Data Protection Training certificate (For User: Gabrielle Mc Kee)

File name description

Document type

Please select which item this attachment applies to

Use this to link attachment to Sites, Methods / Measurements / Persons, etc.

Ethics Review Attachments
To attach files, click on Upload File and press Submit. To delete an attachment, click on Delete in the Actions column.

Participant Information Leaflet (PIL)
A PIL is required as an attachment only if you are recruiting participants, the attachment list on this page will indicate if it is required as an attachment. Download the draft PIL from here, adapt as required to meet the needs of your study and the capabilities of participants. Upload the revised PIL as an attachment.

Guidance : Participant Information Leaflet

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

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

- 1) **File name:** this will allow you to browse in your files and select the file you want to upload.

Please note 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 types of documents that could be uploaded in alphabetical order, select the one that reflects the document you have just selected to upload i.e. Research Integrity Module Certification.
- 4) **Please select which item this attachment applies to:** many attachments are affiliated to a specific person, site or item. Scroll through the selection given and select the name/site/ item that is appropriate in each case.

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

Please note that you may be asked to upload a data protection training certificate twice as:

- A generic attachment (if you answered yes to the Data Protection Training question in the Applicant Section)
- A specific attachment (particular to the TCD research team members i.e. their names) if your application has generated a Data Protection section and you have answered yes to the Data Protection Training question

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.

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 be asked for depending 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 being processed: [link to template here](#)
- 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.

2.13 Declarations

2.13.1 Applicant's declaration

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.

2.13.2 PI declaration

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.

2.13.3 Supervisor declaration

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.

2.13.4 Research Certification

Applications that route to Level 1, and are reviewed solely by the supervisor (for students) or by the staff member themselves (self-declare), will not be deemed to have ethical approval. Rather, it will be stated that the application has received only research certification and not ethical review. Applicants who choose to exercise this option should consider that such self-assessment, rather than review by a REC constituted in accordance with Trinity College regulations, may not prove to be acceptable to journals or granting agencies and should state that they have received research certification but not ethical review.

Signatures and Final Page

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

Confirm and Submit Ethics Application

This section is required for all projects

Do you want to Self Declare this submission? Ticking this option will approve the application automatically without going into the review process.

- No
 Yes

Cancel

Submit

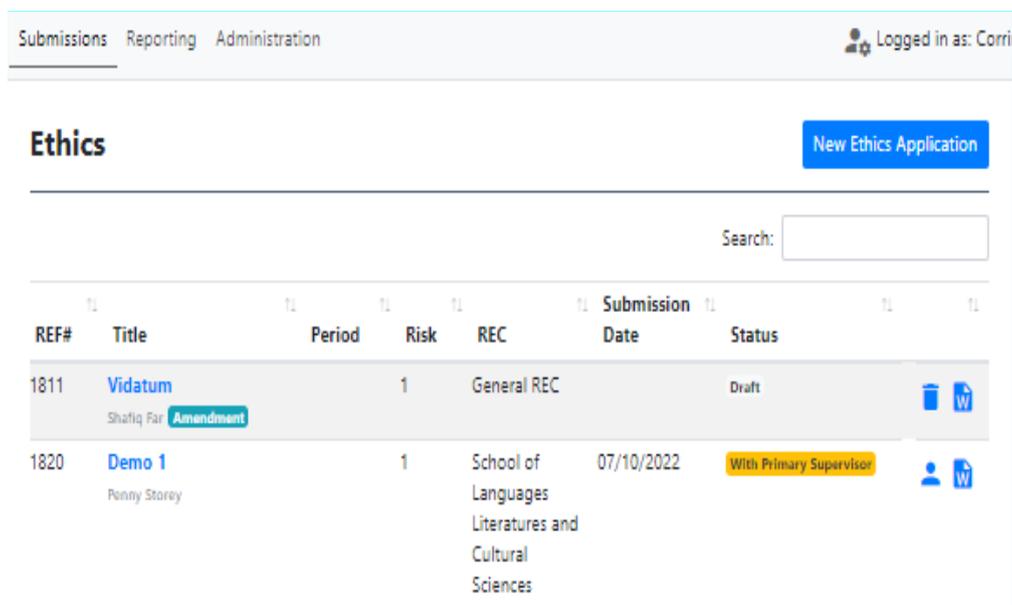
2.14 Word Download

It is advisable to download a word copy of your application and a copy of your corresponding attachments when you have completed and submitted the application. This is to ensure you have an original to compare to for any future corrections that may come back from reviewers.

2.15 Status, Notifications & Outcomes

2.15.1 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:



Submissions Reporting Administration Logged in as: Corri

Ethics

[New Ethics Application](#)

Search:

REF#	Title	Period	Risk	REC	Submission Date	Status
1811	Vidatum <small>Shafiq Far</small> Amendment		1	General REC		Draft
1820	Demo 1 <small>Penny Storey</small>		1	School of Languages Literatures and Cultural Sciences	07/10/2022	With Primary Supervisor

Possible Status Indicators:

- 'With Primary Supervisor' – student application requires supervisor approval
- 'With Principal' – applicant is not PI requires PI approval
- 'Awaiting Recommendation' – reviewers not yet assigned
- 'Awaiting Review' – review not yet complete
- 'Awaiting Approval' – review complete but final outcome not yet decided
- 'Draft' – incomplete OR requires revision by applicant
- 'Approved'
- 'Rejected'

2.15.2 Notifications

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.

PI	Submission type	Title	Approval Step / Role	Notification	link
Penny Storey	Ethics Review	Mooching	Ethics Reviewer	<p>Hello,</p> <p>The following ethics application has been submitted and requires your review. Please note the Application Number for reference below:</p> <ul style="list-style-type: none">Title: MoochingPI: Penny StoreyReference No: 1818 <p>Please login to the system to review and action this item. You can see a link to it from your homepage, under the "Tasks" section.</p> <p>Please do not respond back to the email.</p> <p>TCD Ethics Application System</p>	🔗

2.15.3 Outcomes

In addition, there are several possible outcomes to an ethical application:

- Approve: the application has been successful, and approval granted
- Reject: the application has been refused
- Minor changes: the application has been reset to draft enabling you to do minor corrections
- Major changes: the applications has been reset to draft for you to do major corrections

For both minor and major changes look out for attachments that may have been uploaded summarising the changes being asked for:

- **Minor changes may be summarised in a cover letter from the REC, uploaded as an attachment**
- **Major changes are more likely to be in a word document, perhaps the word copy of the application and/or its attachments with comments.**

2.16 Corrections

If Major/ Minor changes are required by the ethics committee, the application is 'reset to draft' so that the applicant can make the corrections.

Please note that it is not possible to track or highlight changes in the application.

- Minor changes can more than likely be addressed by the applicant writing a cover letter that stipulates changes made and uploading this as an 'other attachment'
- Major changes are likely to require the applicant to highlight changes to show that the corrections have been done. This must be done via the word download of the application form and that of the associated attachments. They will then need to summarise these corrections in a cover letter to confirm they have been done and upload all extra documents as 'other attachments'

2.17 Amendments

These are defined as changes to the details of research that may affect the ethical approval already granted. They are *minor* changes such as:

- the inclusion of an additional member of the research team
- the addition of a new data collection site
- limited changes to the protocol that will not have a major impact on the content of the participant information leaflet, DPIA etc.

Minor changes to the wording of an interview schedule, for example, do not require that an amendment be submitted, unless the content explored is substantially different. Student applicants are advised to discuss and consult with their supervisors when changes of any kind are being contemplated in order to ascertain if they are likely to meet the criteria for an amendment.

If an applicant believes that an amendment is required, they should follow the instruction below:

Project Title: go to submissions, click 'new ethics application', choose Amendment from the pop-up m 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, make the changes to the relevant sections and resubmit.

New Ethics Review ✕

Project Title *

Application Type *

Amendment ▼

Existing Applications *

Reviewing Training ▼

[Submit](#)

[New Ethics Application](#)

026

T1 T1 T1

Status

Approved

Previous 1 Next

Reviewing Training Risk 1

— Amendment to [Reviewing Training](#)

Applicant & Collaborator
Project Details
Attachments

Submit
Save
Exit

Applicant Details

Applicant Name * **Are you applying as a member of staff or a student? ***

Corrinna Moore × ▼

Staff / Student Number

Staff ▼

Email Address

2.18 Post Approval Requirements

After approval has been granted, the applicant will receive **a notification to upload?** :

- Adverse events: reminding them of the need to report these immediately
- End of research review: requesting that an A4 summary is submitted no more than one-year after the granting of approval to summarise the research and/or give an update on status if still ongoing.

Appendix 1: Participant Information Leaflet : Non-Personal Data Template

The Trinity College Dublin Research Ethics Committee has prepared a Participant Information Leaflet template to aid researchers prepare the participant information leaflet for research studies that **do not entail the collection or processing of personal data**.

The form provided is a template **only**: researchers will need to **tailor** this template to their own research studies.

- Some *sections* in the template may not apply depending on the research study. In general, most of the sections specified on the template should be included.
- Some studies may require *items not stated in the 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.

Participant Information Leaflet

Name of Study: [INSERT STUDY TITLE HERE]

Site	
Principal Investigator(s) and Co-Investigator(s) (insert names, titles and contact details)	
Study Organiser/ Sponsor (if applicable)	
Data Controllers	Trinity College Dublin (for research data)
Data Protection Officer	Data Protection Officer Secretary's Office Trinity College Dublin Dublin 2

You must provide an introductory statement.

SAMPLE TEXT:

Example: You are being invited to take part in a research study that is being done by [insert location] by [insert Principle Investigator's name] at [insert site].

Before you decide whether or not you wish to take part, please read this information sheet carefully. Ask [Principle Investigator] any questions. Don't feel rushed or under pressure to make a quick decision. You should understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. You may wish to discuss it with your family, friends or GP.

This leaflet has four main parts:

Part 1 – The Study

Part 2 – Costs, Funding and Approval

Part 3 – Future Research

Part 4 – Further Information

Part 1 – The Study

Why is this study being done?

- Provide an outline of the purpose of your study in lay language. Do not cut and paste directly from the protocol. Avoid technical terms and jargon. If you have to use technical terms ensure that they are explained clearly.

We are undertaking this study to ...

Why have I been invited to take part?

- Explain specifically why that person has been invited.
- State how many participants you are intending to involve and their characteristics (e.g. healthy volunteers, people with specific characteristics (e.g., airline cabin crew).
- Make sure that people without specialist training can understand the words you use. Do not assume words and terms such as 'inclusion', 'exclusion criteria' and 'control' will be understood.

Do I have to take part? Can I withdraw?

Explain:

- that participation is **voluntary**;
- that a decision not to consent will have **no adverse consequences**;
- that consent can be withdrawn. Advise when and how consent can be **withdrawn** (e.g. before data collection is complete) and the impact of any such withdrawal.
- In the event the withdrawal of consent is possible following the completion of data collection, describe the process of withdrawal. For example, at the commencement of an anonymous online survey, the participant may have the facility to generate a unique code that can be provided subsequently as a means to locate data.

SAMPLE TEXT:

Example (for anonymous surveys conducted using an online platform): You do not have to take part in this study. You may withdraw your participation without consequence. If you decide to withdraw before you have completed the survey, you can simply close the browser window, and your data will be erased. If you decide to withdraw subsequently, you can do so until [insert date here] when the data from all participants will be compiled. Should you wish to withdraw before this data, you can do so by contacting [enter name, role and contact details here], and supplying the unique code that you generated at the start of the survey. .

What happens if I change my mind?

- Make it clear that participation in the study is voluntary and that a participant may change their mind if they so wish.
- Inform the participant that if they choose to withdraw from the research, they need not provide an explanation, and that there will be no penalty resulting from withdrawal.

- Outline any limitations that apply to the withdrawal of data:
 - Will it be possible for a participant to withdraw their data after collection has been completed?
 - If the data can be withdrawn after collection, what steps must be taken by the participant; what information must be provided, and to whom?

SAMPLE TEXT:

If you decide to withdraw before you have completed the survey, you can simply close the browser window, and your data will be erased. Once you have completed the survey, it will no longer be possible to identify or erase your data. This is due to the fact that the data are anonymous. The research team have no means of distinguishing your data from those of any the other participants.

How will the study be carried out?

Provide a general overview of the study.

Important questions to address in this section include:

- **When** will the study take place?
- **Where** will the study will take?
- **What** will happen in general terms?
- **How** many individuals will be taking part in the study?

What will happen to me if I decide to take part?

- This is a very important section.
- Participants need to know exactly what they are consenting to. Keep the language simple.
- This section describes what will be involved in the research study from a participant’s point of view.
- Details of the procedures and tests that will be performed – and by whom.
- Indicate the location of data collection (e.g., a study site or via the internet).
- If there are multiple data collection sessions, describe each of them in turn.
- State the period during which the participant will be involved in the research, how often they will be engaged and the duration of each session.
- Clearly state what will be expected of the participant if s/he takes part with adequate detail regarding procedures.
- Outline any plans for long-term monitoring/follow-up.
- Indicate whether there will be any reimbursement or coverage of expenses.

What will happen to my Data?

- State how the data will be used in the research (where they will be transferred or held, what analysis will take place) and in what form (i.e., anonymous). Indicate whether there is an intention to disseminate (publicly) the outcomes of the research?
- Include information on sharing of data, including such details as collaborators and commercial partners.
- Information on how the data will be kept secure should be provided, and who is responsible for ensuring data security. This should include details of restricted access to the data, use of software encryption, firewalls etc.

- You should also give potential participants information on your plans for any data remaining after this specific research project has ended, such as whether they will be destroyed or stored, with consent, for future use.
- If the intention is to retain the data for future use, the likely scope of this use should be indicated. Consider whether anonymous data may be made publicly available. For example:
Your anonymous data will be used mainly by local researchers (if applicable), however they made also be made available through an online database on which there are no access restrictions.

Are there any benefits to taking part in this research?

- Provide information on potential benefits if any, to the participant or others, through taking part.
- If there is no direct benefit to the participant, then this should be stated.

SAMPLE TEXT:

Taking part in this study will not directly benefit you. However, research performed with your anonymous data may help us to better understand [INSERT RESEARCH AREA] and may result in unique knowledge or better tests. This is a long-term research project, so the benefits of the research may not be seen for several years. By participating, you are helping to advance science and medicine for future generations.

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

- This paragraph **always applies**. Provide a fair and honest evaluation of the possible consequences of key research procedures. Remember if you mentioned a risk to the research ethics committee, the participants also need to know about it.
- Risks, including any discomforts must be clearly explained. Precautions taken to minimise risks should be stated.
- The participant should be advised that he/she is entitled to seek a second opinion.
- State clearly any potential for physical, emotional, psychological harm and/or stress, arising from participation, and the measures that have been put in place to minimise such potential. For example, what happens if questions are stressful? Is counselling provided?
- Potential breach of confidentiality should be considered as a risk.

SAMPLE TEXT (in relation to data risks):

Note, there can be considerable variety in respect of data risk, depending on the nature of the study and type of data that is captured and subsequently processed as a consequence.

- *There is a risk that a connection to your identity could be made. Great care will be taken to ensure the confidentiality of all data and the risk to participants of a breach of confidentiality is considered very low [AMEND AS APPROPRIATE].*

What happens if something goes wrong when I'm taking part in the study? (May not apply)

- This paragraph may not apply to your study.

- If your study involves a risk and you have measures in place if the risk does materialise, let the participant know; e.g. counselling in case of psychological distress.

SAMPLE TEXT:

If you have experienced any distress as a result of taking part in this study, contact details for the Trinity College Counselling Service and the Samaritans are provided below. If you have any questions about the study please contact a member of the research team (contact details can be found below).

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

- Indicate whether:
 - The **results of the research** will be reported to the participant. Since no personal or identifying information will be collected, in most cases, there will be no means of conveying such information directly to individual participants.
- Important items to address in this section include:
 - How the **results of the research** will be disseminated e.g. journals, scientific conferences.

SAMPLE TEXT:

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

Part 2 – Costs, Funding and Approval

Has this study been approved by a research ethics committee?

Provide details of the **research ethics committee** that gave ethical approval to the research including:

- The **name and contact details** of the committee that gave ethical approval to the research (does not need to be a named individual);
- Whether any of the persons carrying out the research have a **link** to the committee or the institution behind the committee;
- The **date** ethical approval was given by the committee;
- **Reporting arrangements** agreed with the committee;
- Any **conditions** attached to the research by the committee.

SAMPLE TEXT:

*Yes, this study has been approved by **[INSERT NAME(S)] [JOINT, IF APPROPRIATE]** Research Ethics Committee. Approval was granted on **[INSERT DATE]**.*

Who is organising and funding this study? Will the results be used for commercial purposes?

Outline the funding for the study

Questions to consider answering in this paragraph:

- Who is conducting the research?
- Who is funding the research?
- Are you getting a grant to do this research?
- Are you conducting the research for the purposes of obtaining an academic qualification?
- Is a commercial enterprise funding this study?
- Are you being paid to recruit patients to this study?
- Will the results be disclosed for commercial purposes?

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

State the costs of participation and any reimbursements or compensation to be provided (if any).

SAMPLE TEXT:

We are not paying participants to take part in the study. You will however be reimbursed for travel expenses to the testing location.

Part 3 – Future Research

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

- State whether you intend to seek the participant's consent for use of his/her data in **future research studies** and, to the greatest extent possible, describe in lay terms the intended future uses of the research participants' data.
- Explain to participants if you are seeking only permission for their data to be used for the current study, or if you are seeking permission to store their data for possible use in future research.
- Explain if future research will be yours, or whether it could be **someone else's research**.
- Make it clear that the granting of consent for future use is a voluntary step
- Indicate whether it will be possible for the participant to withdraw their consent for use of the data in future research, at a later date.
- If it is possible for the participant to withdraw their consent at a later date, indicate the way in which this can be done.

Part 4 – Further Information

Who should I contact for information or complaints?

SAMPLE TEXT:

If you have any concerns or questions, you can contact:

- *Principal Investigator: [INSERT CONTACT DETAILS HERE].*
- *Data Protection Officer, Trinity College Dublin: Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: www.tcd.ie/privacy.*

Giving consent

SAMPLE TEXT:

If you would like to take part in this study, you will be asked to sign the Consent Form on the next page. You may download a copy of this information leaflet and the signed Consent Form to keep.

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 xxxx'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 guidance document, only one term is used to convey a particular meaning. The specific terms were selected based on adequacy, and the manner of their current use across Trinity in the context of ethics applications. In this section, the main terms are defined.

- **Adverse Event:** is any event that causes harm or distress in the context of research involving animal or human participants. The risk section in the application form requires that applicants to identify the potential for adverse events and indicate the steps to be taken to mitigate against any such events. It is requirement when ethical approval has been granted that adverse events are reported to the approving ethics committee. Details of adverse event reporting policy currently under development.
- **Amendment:** Changes made to an ethics application after receiving approval.

- **Applicant:** The applicant is the **one** named researcher who has primary responsibility for the ethics application. This person will receive official correspondence concerning the application, including the outcome of review. It is expected that this person will respond to any requirements arising from review. In most cases (including submissions by students), the applicant will also be Principal Investigator (PI) for the project (see below for PI definition). In some large projects, the role of applicant may be delegated to another member of the research team, who is not the PI. In such cases, the PI must tick the appropriate declaration, and approve the application, as part of the submission process (See PI below for more information).
- **Attachment:** An attachment is any additional document required to be submitted with the application. For example, when the answer is yes to the question: *Will consent be taken from the participant?* the system will register that an attachment of the consent form is required. An attachment tab will appear at the top of the page. When the application form is otherwise complete, opening the attachment tab will reveal a list of all the attachments that are required and an interface for their uploading. Submission of the application will only be possible when all the attachments on this list have been uploaded. (See section 3.5 below for further detail on the attachments that may be required).
- **Collaborator:** The term collaborator is the generic term used in the application for all other members of the project's research team. This term is synonymous with investigator, co-investigator, co-applicant and includes Academic/ Clinical/Professional/ Industrial Collaborator and Public or Participant Collaborator
- **Committee Review:** This is the term used in the present document for the traditional means of evaluation by a research ethics committee, see also expedited review and Section 4 below for further detail).
- **Expedited Review:** In line with the [Policy for Good Research Practice](#) all research ethics committee have a pathway that permits certain projects to be reviewed in a fast-track manner for example those that have ethics approval from other recognised research ethics committees (see Section 4below for further detail).
- **Principal Investigator:** Principal investigator (PI) is the term used to identify the person responsible for the preparation, conduct and administration of a project and (if applicable) of a corresponding research grant. This person will usually also be the one responsible for the ethics application (i.e., the Applicant). Most students will be both the PI and the Applicant. In such cases, a supervisor declaration section will be generated. For the application to proceed, this must be completed by the primary supervisor. In some large projects, the role of applicant may be delegated to another member of the research team, who is not the PI. In such cases, the PI must sign the appropriate declaration, and approve the application, as part of the submission process (See also Applicant entry above).
- **Project:** Throughout this documentation, the term project applies to the research that is related to an ethics application. In most cases synonymous with study, thesis, proposal.
- **Participant/ potential participants:** This term is used synonymously for subject, data subjects, individuals, animals.

- **Administrative Data:** This is administrative information collected through the course of the project which is not directly related to the aims and objectives of the study. It is not research data (see below Research Data). It may include Personal Data (as defined under the General Data Protection Regulation and are subject to being processed, retained and destroyed in line with Trinity policies. These data may include schedules, contact details. 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