**RESEARCH ETHICS APPLICATION FORM – reflectimg REAMS**

**NB: This file is for information only, to facilitate consideration of the REAMS application form questions. It has been made available because REAMS is a dynamic system in which some questions are only revealed when triggered by responses to key filter questions.**

**Applications CANNOT be made using this Word copy; they must be made using the online REAMS application form at** [**https://ethics.tcd.ie**](https://ethics.tcd.ie)**.**

|  |
| --- |
| * **Ethical approval for research** **All research is subject to ethical scrutiny. However, only research involving human participants or their data or research involving animals requires ethical approval.** Before you start your research confirm that you need ethical approval for your research. See the checklist: [Definitions of Research NOT Requiring Ethical Approval.](https://www.tcd.ie/research/support/assets/doc/Definitions%20of%20Research%20Requiring%20Ethical%20Approval.docx)  Get familiar with:  * Trinity’s [Policy on Good Research Practice](https://www.tcd.ie/research/assets/pdf/Policy%20on%20Good%20Research%20Practice_1.1.pdf) * Data Protection at Trinity:   + Trinity’s [Data Protection Policy and Handbook](https://www.tcd.ie/dataprotection/research/). Official Trinity templates for the required consent forms and PILs can be found [here](https://www.tcd.ie/dataprotection/trinitycollegetemplates/).   + GDPR [training is provided by the Data Protection Office](https://www.tcd.ie/dataprotection/training/) for all those processing or conducting or supervising research involving Personal Data of Participants * Research Integrity at Trinity:   + PhD candidates are automatically enrolled in the Blackboard [CA7000 Research Integrity](https://tcdud-my.sharepoint.com/:x:/g/personal/genadgso_tcd_ie/EQ0IAiLJxAFHtlD5f0J6LOQBVJS9T31h-FPkQN_5mWZJYA?e=8xRJks%2F) module   + All other staff and students should avail of the [Epigeum Research Integrity training](https://www.tcd.ie/research/support/epigeum.php) * Any other requirements specific to your faculty, school or discipline.  Ensure the following are in place:  * Enough time: depending on the nature of the research, applications can take a long time to complete * Complete Trinity’s training modules for Data Protection and Integrity in Research * Permissions to contact participants are in place, recruitment materials and consent forms are prepared * Garda Vetting completed if required * Data Collection instruments developed * Interventions or experiments designed * Confirmation whether your research qualifies as Health Research * If you are using non-Trinity sites or collaborating with researchers from another institution you may also need:   + Ethics approvals from committees outside of Trinity where necessary   + Licences or permits to access non-Trinity sites and/or secondary data sources   + Data Protection Risk or Impact Assessments (DPR/I As) for non-Trinity sites   + Data sharing contracts   **Prepare any relevant documents pertaining to the above as they will be required as attachments for the application.** Data Protection Review  * Under current procedures, the Data Protection review process is decoupled from the College’s Research Ethics Application Management System (REAMS) and will happen outside REAMS. Your REAMS application cannot proceed to the relevant REC until this Data Protection Review process has occurred. * There are 6 questions within REAMS that may trigger a Data Protection Review. The Data Protection Office (DPO) has provided information on this review process [here](https://www.tcd.ie/dataprotection/assets/202310_DPO_REAMS_reviews.pdf). * Once you have completed your Data Protection Review, the DPO will provide you with a ‘DPO-letter of completion’ which you must upload as part of your REAMS application. * NB. Your application CANNOT be submitted until you upload your letter of completion from the DPO.  Guidance/support Some help text is provided within the REAMS application form. However, more comprehensive guidance manuals and videos are provided on the [REAMS website](https://www.tcd.ie/research/support/ethics-approval.php). The two core supporting documents are:   * [Background manual for using REAMS. Read this before starting your application.](https://www.tcd.ie/research/support/assets/pdf/REAMs%20Background%20Manual%20181223.pdf) * [Manual for applicants using REAMS (question by question guide). Read this while making an application.](https://www.tcd.ie/research/support/assets/pdf/REAMs%20Making%20An%20Application%20Manual%2018.12.23%20.pdf) |

**Before beginning your REAMS application – confirmation statement**

Not all research on humans and/or their data or animals requires ethical approval. Check if your research requires ethical approval by referring to this set of criteria [here.](https://www.tcd.ie/research/support/ethics-approval.php)  
  
Please note that your application may require assessment from the College Data Protection Office. This could result in an extended application process which should be considered from the outset. Please review the information provided [here](https://www.tcd.ie/dataprotection/assets/pdf/REAMSreview/202310_DPO_REAMS_review.pdf) before commencing your application.  
The six questions that may trigger DPO Review are highlighted in yellow in this file: Questions 2.1.8, 2.1.9, 2.2.9, 2.2.14, 10.2.2 and 10.2.4.

|  |  |
| --- | --- |
|  | **I confirm that I have checked the relevant criteria and reviewed the new data protection process.** |

**Project title**

|  |
| --- |
|  |

**Application type**

|  |  |  |  |
| --- | --- | --- | --- |
|  | New |  | Amendment |

**Overview**

The body of this application form contains the sections shown below.

|  |  |  |
| --- | --- | --- |
| **SECTION** | | **STATUS** *Note that within mandatory sections there may be some questions that do not apply to all applications* |
| **1.** | **Applicant and collaborators** | Mandatory for all applications |
|  | 1.1 Applicant details |
|  | 1.2 Details of Trinity collaborator(s) |
|  | 1.3 Details of non-Trinity collaborators |
| **2.** | **Project details** | **Mandatory for all applications Please take great care in answering these questions, consulting the guidance document as you proceed, because many are filter questions that open/close other sections of the application.** |
|  | 2.1 Main project details |
|  | 2.2 Details of human participants and their data |
|  | 2.3 Research sites and data sources |
|  | 2.4 Outline of project methods |
| **3.** | **Animal research** | Not included in this file. |
| **4.** | **Risks, benefits, confidentiality and conflict** | Mandatory for all applications |
|  | 4.1 Risk or harm to the researcher |
|  | 4.2 Risk or harm to site, environment or society |
|  | 4.3 Risk or harm to participants |
|  | 4.4 Participant benefits and confidentiality |
|  | 4.5 Conflict of interest (arising from personnel) |
| **5.** | **Human biological samples** | Required if the project utilizes human biological samples |
| **6.** | **Funding and conflict of interest** | Required if the project is funded |
|  | 6.1 Funding details |
|  | 6.2 Conflict of interest (arising from funding or commercialization) |
| **7.** | **Sampling and recruitment** | Required if project data are to be collected from primary sources |
| **8.** | **Consent** | Required if the project requires consent or assent from participants |
| **9.** | **Health research** | Required if the project is Health Research as defined in the Health Research Regulations |
| **10.** | **Data protection** | Required if the data being processed could directly or indirectly identify a living individual |
|  | 10.1 Opening questions |
|  | 10.2 Data protection information |
|  | 10.3 Processing risk |
|  | 10.4 Closing section |
| **11.** | **Attachments** | The attachments (appendices) will vary depending on the project. Mandatory attachments are flagged by REAMS. Examples (non-exhaustive) are flagged in **green** throughout this file. |
|  | **Declarations** | Applicant’s declaration is mandatory for all applications. PI declaration is required if applicant is not the PI. Student applicants require supervisor’s declaration. |
|  | Signature and final page (applicant’s declaration) |
|  | Principal investigator (PI) declaration |
|  | Supervisor declaration |

**1. APPLICANT AND COLLABORATORS**

**1.1 APPLICANT DETAILS**

**The APPLICANT DETAILS subsection must be completed for all projects**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1.1.1 Applicant name** *(Title, Given name, FAMILY NAME)* | |  | **1.1.2 Are you applying as a member of staff or a student?** | | | | | | | | | |
|  | |  |  | | Staff | |  | | Student | | | |
| **1.1.3 Staff / Student number** | |  | **1.1.4 Email address** | | | | | | | | | |
|  | |  |  | | | | | | | | | |
| **1.1.5 School / Department** | |  | **1.1.6 Role on the project** | | | | | | | | | |
|  | |  |  | Principal investigator | | | |  | | Investigator (non-PI) |  | Other |
| **1.1.7 Primary employer (if not Trinity)** | |  | **1.1.8 Other affiliations (if applicable)** | | | | | | | | | |
|  | |  |  | | | | | | | | | |
| **1.1.9 Course (for student applicant only)** | |  | **1.1.10 Part time / full time** | | | | | | | | | |
|  | PhD |  |  | | | Part-time | | | | | | |
|  | Professional doctorate |  |  | | | Full-time | | | | | | |
|  | Masters by research |  |  | | |  | | | | | | |
|  | Taught masters |  |  | | |  | | | | | | |
|  | Undergraduate |  |  | | |  | | | | | | |

**1.1.11 I have read and understood Trinity's policy on good research practice**

*Refer to the following document:* [*Policy on Good Research Practice*](https://www.tcd.ie/media/tcd/about/policies/pdfs/Policy-on-Good-Research-Practice_1.1.pdf)*.*

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

**1.1.12 I have completed a TCD Research Integrity Training Module**

*If YES, you are required to attach your Research Integrity Training certificate as an appendix to this ethics application.   
Ph.D. students must have completed CA7000: Research Integrity and Impact in an Open Scholarship Era.*  
*See link:* [*Research integrity training for PhD students*](https://www.tcd.ie/dataprotection/training/)*. (MANDATORY for PhD students).  
See link:* [*Epigeum research integrity training (staff and other students)*](https://www.tcd.ie/research/support/epigeum.php)*. (AVAILABLE for all).*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Yes |  | No |  | Not applicable |

**1.1.13 I have completed a Data Protection Training module within the last 24 months***If YES, you are required to attach your Data Protection Training certificate (dated within the last 24 months) as an appendix to this ethics application.*

*See link:* [*Data protection training module*](https://www.tcd.ie/itservices/vle/kb/overview-GDPRtraining.php)*. Certificates for other appropriate training (e.g. HSeLanD) may also be accepted. For Ph.D. students, the certificate for* CA7000: Research Integrity and Impact in an Open Scholarship Era *fulfils this requirement.*

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

**1.2 DETAILS OF TRINITY COLLABORATOR(S)**

**The DETAILS OF TRINITY COLLLABORATOR(S) subsection must be completed if the project team includes other TCD staff/students, besides the applicant.**

*Collaborators are members of the research team. Copy and paste the subsection below (1.2.1-1.2.5) as many times as required for completion by each TCD collaborator.*

*In all cases,* ***primary supervisors*** *must append a Data Protection Certificate (dated within the last 24 months).   
For projects that include the processing of personal data,* ***all Trinity collaborators*** *are required to append a Data Protection Certificate (dated within the last 24 months).*

|  |  |  |
| --- | --- | --- |
| **1.2.1 Role(s) on the project** |  | TCD principal investigator |
|  | Primary supervisor |
|  | TCD co-supervisor |
|  | Stakeholder (academic/clinical/professional/industrial collaborator) |
| **1.2.2 Name** *(Title, Given name, FAMILY NAME)* |  | |
| **1.2.3 Email address** |  | |
| **1.2.4 TCD affiliation (*e.g.* School/ Department/ Centre)** | *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. E.g. “School of Medicine. Clinical collaborator”.* | |
| **1.2.5 Job title/role within TCD** |  | |

**1.3 DETAILS OF NON-TRINITY COLLABORATOR(S)**

**The DETAILS OF NON-TRINITY COLLABORATOR(S) subsection must be completed if the project team includes non-TCD personnel.**

*Collaborators are members of the research team. Copy and paste the subsection below (1.3.1-1.3.6) as many times as required for completion by each non-TCD collaborator.*

|  |  |  |
| --- | --- | --- |
| **1.3.1 Name** *(Title, Given name, FAMILY NAME)* |  | |
| **1.3.2 Email address** |  | |
| **1.3.3 Role(s) on the project** |  | Non-TCD principal investigator |
|  | Non-TCD co-supervisor |
|  | Stakeholder (academic/clinical/professional/industrial collaborator) |
|  | Public/participant collaborator |
| **1.3.4 Primary/relevant non-TCD affiliation (name of organization)** | *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. E.g. “Murphy’s Pharmacy, Anytown. Clinical collaborator”.* | |
| **1.3.5 Job title/role within non-TCD organization** |  | |
| **1.3.6 Country/countries** |  | |

**2. PROJECT DETAILS**

**2.1 MAIN PROJECT DETAILS**

**The MAIN PROJECT DETAILS subsection must be completed for all projects.**

*Read the* [*Guidance Document*](https://www.tcd.ie/research/support/assets/pdf/REAMs%20Making%20An%20Application%20Manual%2018.12.23%20.pdf) *closely while completing this subsection   
With regard to the question on whether the project involves animals or humans (or their data), 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.*

*Answers in this subsection may influence whether other questions need to be completed or not.*

2.1.1 Title of project

*On REAMS, this field will be pre-populated with the title you chose at the outset, but it can be modified here.   
If your project is a phased study where ethics approval will be sought repeatedly (i.e. different REAMS applications) for the various phases rather than all in a single application), the titles of the phases should each comprise a common stem followed by the phase details. E.g. "Determination of XXX: Phase 1 – Questionnaire", "Determination of XXX: Phase 2 – Focus groups". See “Phased Research” on p. 25 of the* [*Guidance Document*](https://www.tcd.ie/research/support/assets/pdf/REAMs%20Making%20An%20Application%20Manual%2018.12.23%20.pdf)*.*

|  |
| --- |
|  |

Project timeframe

*If you are collecting data from multiple sites, enter the earliest start date and the latest possible end date, when all sites are considered collectively.*

|  |  |
| --- | --- |
| **2.1.2 Data collection start date:** |  |
|  |  |
| **2.1.3 Data collection end date:** |  |
|  |  |
| **2.1.4 Project end date:** |  |

2.1.5 Does the project involve animals or human data subjects/participants?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Animals |  | Humans (or their data) |

*If the project involves animals, you should apply to the Animal Research Ethics Committee instead of your School or Faculty Committee. If the project involves both human and animal participants, two separate applications are required.*

*[Questions 2.1.6 and 2.1.7 relate to animal projects and are not included in this Word file.]*

2.1.8 Could the research have detrimental legal, economic or social consequences for either the participant(s) or their establishment(s)?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

*YES indicates Level 3 [Faculty] REC approval is required.   
YES also indicates that a DPO review must be undertaken, using the* [*data protection review template*](https://www.tcd.ie/dataprotection/assets/docs/reviewtemplate/202309_DP_Review_template.docx)*. You should email the completed template to* [*dataprotection@tcd.ie*](mailto:dataprotection@tcd.ie) *along with data protection training certificate(s) for the research team member(s), using the email subject line “data protection review”, and await instructions and feedback from the DPO (who may require further documentation) in order to obtain a DPO Review Letter of Completion. If the response to this question is YES, it will be necessary to include the DPO Review Letter of Completion as an appendix to this application form. You cannot submit your application to the REC until this letter has been received from the DPO and appended.*

2.1.9 Intentions of the project

|  |  |  |
| --- | --- | --- |
| Does the project: | **YES** | **NO** |
| 1. Involve deception? |  |  |
| 2. Intend to uncover additional illegal activity? |  |  |
| 3. Explore a topic that is potentially intrusive or is it research that is harmful or may endanger participants? |  |  |
| 4. Have a military role? |  |  |
| 5. Have a dual purpose that could be misdirected to do harm?  *If YES, see ‘Dual Purpose’ in* [*TCD guidance on completion of the application form*](https://www.tcd.ie/research/support/assets/pdf/REAMs%20Making%20An%20Application%20Manual%2018.12.23%20.pdf) *for additional requirements.* |  |  |
| 6. Involve none of 1-5 above? |  |  |

*If any of 1-5 apply, Level 3 [Faculty] REC approval is required.   
If 1 and/or 3 applies, a DPO review must be undertaken, using the* [*data protection review template*](https://www.tcd.ie/dataprotection/assets/docs/reviewtemplate/202309_DP_Review_template.docx)*. You should email the completed template to* [*dataprotection@tcd.ie*](mailto:dataprotection@tcd.ie) *along with data protection training certificate(s) for the research team member(s), using the email subject line “data protection review”, and await instructions and feedback from the DPO (who may require further documentation) in order to obtain a DPO Review Letter of Completion. If 1 and/or 3 applies, it will be necessary to include the DPO Review Letter of Completion as an appendix to this application form. You cannot submit your application to the REC until this letter has been received from the DPO and appended.*

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

|  |
| --- |
|  |

2.1.11 Lay summary

Please include background/rationale/justification, research approach, study design. *This is a high-level, lay overview only; exclude excessive details of measurement instruments and intervention and analysis if applicable, as these will be provided/appended later. (Word limit: 250 words)*

|  |
| --- |
|  |

2.1.12 Identify all countries where data are collected or processed

|  |
| --- |
|  |

2.1.13 Data type  
Which of the following does the project involve?

|  |  |  |
| --- | --- | --- |
|  | **YES** | **NO** |
| 1. Human participants and/or their data, but no biological samples |  |  |
| 2. Human biological samples that are not from patients and that have been taken in a non-intrusive manner |  |  |
| 3. Human biological samples from patients *YES indicates Level 3 [Faculty] REC is required.* |  |  |
| 4. Human biological samples taken in an invasive manner  *YES indicates Level 3 [Faculty] REC is required.* |  |  |
| 5. Human biological samples of any size or type that could have impact on future treatment (*e.g.* human DNA sequencing)  *YES indicates Level 3 [Faculty] REC is required.* |  |  |

2.1.14 Is the project funded?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

**2.2 DETAILS OF HUMAN PARTICIPANTS AND THEIR DATA**

**This subsection is required for all projects involving data on humans.**

**2.2.1 Is your project a phased study?**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

**2.2.2** If YES, please identify the parent project, *i.e.* the project that is the first phase in the sequence. *(If the current application is for the first project in a distinctly phased sequence of interdependent projects, please leave this field blank. If this application is for the second or subsequent phase, then please insert the parent project below. In the online REAMS interface, your previous applications on REAMS will appear in a dropdown menu for selection.)*

|  |
| --- |
| **Parent study project title** |
|  |

**2.2.3 The project uses data from** (choose one)**:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Primary sources only |  | Secondary sources only |  | Both primary & secondary sources |

If primary sources will be used, the participant information leaflet (PIL) must be appended.   
*See College templates, noting the different PIL templates for health research and non-health research:* [*https://www.tcd.ie/dataprotection/trinitycollegetemplates/*](https://www.tcd.ie/dataprotection/trinitycollegetemplates/)*.*

**2.2.4 Will you obtain consent from participants for their participation and for the use of their data? (In the case of children – consent from a parent/legal guardian. In the case of adults who lack capacity – consent from a proxy.)**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If YES, the relevant consent/assent documentation must be appended to this application.   
*See College templates at* [*https://www.tcd.ie/dataprotection/trinitycollegetemplates/*](https://www.tcd.ie/dataprotection/trinitycollegetemplates/)*. If the project is health research, you must use the Explicit Consent template unless one of the exceptions for its use are met. (See Health Research section of this application form: 9.1.)*

**2.2.5.** If NO, please provide further information.

|  |
| --- |
|  |

**2.2.6 Will payment be made to research participants?***This question only appears if you selected “primary” or “both primary & secondary” sources in 2.2.3.  
(Choose only one payment option below. If more than one applies (*e.g. *different approaches for various participant categories), then choose the option representing the most generous payment in your project.) If paying participants, please refer to* [*TCD's Gift Voucher Policy*](https://www.tcd.ie/financial-services/assets/pdfs/Gift_Voucher_Policy_Log_2016.pdf)*.*

|  |  |
| --- | --- |
|  | No |
|  | Yes – standard gratuity with or without expenses |
|  | Yes – a higher value gratuity with or without expenses |

**2.2.7** If YES – A HIGHER VALUE GRATUITY, please provide further information.

|  |
| --- |
|  |

**2.2.8 Is the project health research as defined in the Health Research Regulations 2018 as amended (HRR)?**

*HRB guidance on Health Research Regulations 2018:* [*https://www.hrb.ie/funding/gdpr-guidance-for-researchers/health-research-regulations-2018/*](https://www.hrb.ie/funding/gdpr-guidance-for-researchers/health-research-regulations-2018/) *HRCDC guidance on amendments to the Health Research Regulations:* [*https://hrcdc.ie/guidance/*](https://hrcdc.ie/guidance/)

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

**2.2.9** If YES, does the project require a Consent Declaration form under the Health Research Regulations (2021)? *(Please note that this is a specific declaration for health research under particular circumstances, and not a conventional consent form.)*

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

*If YES, the completed consent declaration application form will need to be appended to this application.   
Note that any application to the Health Research Consent Declaration Committee for a consent declaration must be carried out in consultation with TCD's Data Protection Officer.*

*If YES, a DPO review must be undertaken, using the* [*data protection review template*](https://www.tcd.ie/dataprotection/assets/docs/reviewtemplate/202309_DP_Review_template.docx)*. You should email the completed template to* [*dataprotection@tcd.ie*](mailto:dataprotection@tcd.ie) *along with data protection training certificate(s) for the research team member(s), using the email subject line “data protection review”, and await instructions and feedback from the DPO (who may require further documentation) in order to obtain a DPO Review Letter of Completion.  
If YES, it will be necessary to include the DPO Review Letter of Completion as an appendix to this application form. You cannot submit your application to the REC until this letter has been received from the DPO and appended.*

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

*Note: This question only applies to* ***research*** *data. Research data are the data required to meet the aims and objectives of the project. A more detailed definition is available in the* [*Guidance document*](https://www.tcd.ie/research/support/assets/pdf/REAMs%20Making%20An%20Application%20Manual%2018.12.23%20.pdf)*.  
See 2.2.12 below for other project information that has personal data.)*

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

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

*Note: This question only applies to* ***research*** *data. Research data are the data required to meet the aims and objectives of the project. A more detailed definition is available in the* [*Guidance document*](https://www.tcd.ie/research/support/assets/pdf/REAMs%20Making%20An%20Application%20Manual%2018.12.23%20.pdf)*.  
See 2.2.12 below for other project information that has personal data.)*

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

**2.2.12 Are you processing any personal data for study administration purposes (*e.g.* contact details, consent forms)?**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

**2.2.13** If YES, please outline how you will store the information, keep it confidential, and destroy it in line with the data retention policy. *Note: This section relates to measures for the personal data that are processed for administrative purposes. (Measures for personal data that are research data will be described later. See Section 10.2.)*

|  |
| --- |
|  |

**2.2.14 Which of the following best describe(s) the general characteristics of the target population?** *(Choose ALL that apply.)*

|  |  |
| --- | --- |
|  | (a) Adults currently not at risk of vulnerability |
|  | (b) Adults at risk of vulnerability *(YES indicates Level 3 [Faculty] REC is required. YES also indicates that the project must undergo DPO review and a DPO Review Letter of Completion must be appended.)* |
|  | (c) Participants who require support to give consent *(If YES, may need to apply to Faculty REC, Level 3, depending on other characteristics of study. See* [*TCD guidance on completion of the application form*](https://www.tcd.ie/research/support/assets/pdf/REAMs%20Making%20An%20Application%20Manual%2018.12.23%20.pdf)*.)* |
|  | (d) Children (< 18 years) *(YES indicates Level 3 [Faculty] REC is required. YES also indicates that the project must undergo DPO review and a DPO Review Letter of Completion must be appended.)* |
|  | (e) Participants who have a dependent relationship with the researcher *(YES indicates Level 3 [Faculty] REC is required.)* |
|  | (f) Students of Trinity *(If YES, evidence of access permission must be appended.)* |
|  | (g) Staff of Trinity *(If YES, evidence of access permission must be appended.)* |

*If YES to (b) and/or (d), a DPO review must be undertaken, using the* [*data protection review template*](https://www.tcd.ie/dataprotection/assets/docs/reviewtemplate/202309_DP_Review_template.docx)*. You should email the completed template to* [*dataprotection@tcd.ie*](mailto:dataprotection@tcd.ie) *along with data protection training certificate(s) for the research team member(s), using the email subject line “data protection review”, and await instructions and feedback from the DPO (who may require further documentation) in order to obtain a DPO Review Letter of Completion.  
If YES to (b) and/or (d), it will be necessary to include the DPO Review Letter of Completion as an appendix to this application form. You cannot submit your application to the REC until this letter has been received from the DPO and appended.*

*If staff and/or students of Trinity will be participants ((f) or (g) above), see information at* [*https://www.tcd.ie/communications/what-we-do/internal-communications/email-protocol-for-staff-and-student-emails/*](https://www.tcd.ie/communications/what-we-do/internal-communications/email-protocol-for-staff-and-student-emails/) *for blanket emails to all staff and/or all students, and* [*https://www.tcd.ie/itservices/our-services/trinity-mailing-lists/*](https://www.tcd.ie/itservices/our-services/trinity-mailing-lists/) *for emails to selected TCD mailing lists.*

**2.2.15 Only required if project is health research (2.2.8 = YES). Do any of the following further describe the characteristics of the target population?** *(Choose all that apply.)*

|  |  |
| --- | --- |
|  | (i) Participants recruited because of a **current or previous** medical condition or treatment |
|  | (ii) Participants recruited because of a **current or previous** non-medical condition or treatment |
|  | (iii) Healthy controls/participants, *e.g*. those used in the control arm of a health trial study |
|  | (iv) Other |

**2.2.16** If OTHER, please describe.

|  |
| --- |
|  |

**2.2.17 List the inclusion/ exclusion criteria for selection of project participants.** *If the study has a participant information leaflet (PIL), the criteria in the PIL should be consistent with those in this section (though the PIL may use simplified language), so that prospective participants can identify whether they are eligible or why they have been chosen.*

|  |
| --- |
|  |

**2.3 Research sites and data sources**

**This subsection is required for all projects involving data on humans.**

*If there are more than four sites/sources, copy and paste the table below (2.3.1-2.3.5) as many times as required.*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Site/Source 1** | | **Site/Source 2** | | **Site/Source 3** | | **Site/Source 4** | |
| **2.3.1 Name of data collection site/ source.** |  | |  | |  | |  | |
| **2.3.2 Does this site/source require a licence to use, permission to access and/or external ethics approval?** *(Choose all that apply.) For each site, any applicable documentation (licence/permission/approval) must be appended to this application.* |  | N/A: No licence/ permission/ approval is required |  | N/A: No licence/ permission/ approval is required |  | N/A: No licence/ permission/ approval is required |  | N/A: No licence/ permission/ approval is required |
|  | Licence |  | Licence |  | Licence |  | Licence |
|  | Permission to access |  | Permission to access |  | Permission to access |  | Permission to access |
|  | Site/source ethics approval required and obtained |  | Site/source ethics approval required and obtained |  | Site/source ethics approval required and obtained |  | Site/source ethics approval required and obtained |
|  | Site/source ethics approval required but not yet obtained from this site |  | Site/source ethics approval required but not yet obtained from this site |  | Site/source ethics approval required but not yet obtained from this site |  | Site/source ethics approval required but not yet obtained from this site |
| **2.3.4 Name source of permission (*e.g*. name of licensor, ethics committee, person who grants permission for this site/source) or explain why permission is not required.** |  | |  | |  | |  | |
| **2.3.5 Was a data protection impact assessment (DPIA) required at this site/source?** *If YES, please append the external DPIA.* |  | Yes |  | Yes |  | Yes |  | Yes |
|  | No |  | No |  | No |  | No |

**2.4 OUTLINE OF PROJECT METHODS**

**This subsection is required for all projects involving data on humans.**

**2.4.1 Outline the data collection methods.**

*In this question you are required to provide a high-level outline of the type(s) of data collection methods that will be used (e.g., interview, survey, questionnaire, blood samples etc.). In the next question (2.4.2) you will be asked to name and describe any specific instruments that will be used.*

|  |
| --- |
|  |

**2.4.2 Methods/measurements.** *(Word limit = 100 words for each.)*  
*Please add as many additional rows to the table in 2.4.2 as may be required to name and describe each instrument, sample, measurement and test you will use (one per row).  
When describing an instrument of data collection, indicate if the instrument (a) is currently usual practice, or (b) has been adapted from usual practice (explain how it differs, if applicable), or (c) is completely new to the cohort being researched. (Example: Student survey utilising Trinity annual student survey form with additional section of questions to evaluate new changes in practice.)  
The individual tools identified here should be provided as appendices (questionnaires, interview guides, observation schedules, data extraction forms, etc*.*).*

|  |
| --- |
|  |
|  |

**2.4.3 Does your project use any of the methods listed in 1-6 exclusively?** *Choose the single method that applies, or mark NO.*

|  |  |
| --- | --- |
|  | 1. Quality assurance studies *May facilitate classification as Level 1, though other parameters may raise risk level.* |
|  | 2. Anonymous surveys *May facilitate classification as Level 1, though other parameters may raise risk level. Note that including free text boxes in a survey may compromise its anonymity if respondents could include information that might indirectly identify them.* |
|  | 3. Unrecorded and anonymous observation of individuals in public areas *May facilitate classification as Level 1, though other parameters may raise risk level.* |
|  | 4. Audits of standard practices or tests *May facilitate classification as Level 1, though other parameters may raise risk level.* |
|  | 5. Information, documents or data which are in the public domain |
|  | 6. A data source not publicly available but which you have permission to use |
|  | No |

2.4.4 Does the project include an intervention?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

*If YES, REAMS automatically routes to Level 3 [Faculty] REC. If project is clearly low risk despite intervention, discuss before submission.*

**2.4.5** If YES,

(a) Which of the following best describes the intervention? (Choose one.)

|  |  |
| --- | --- |
|  | 1. Health-related (including psychology, social care) |
|  | 2. Educational |
|  | 3. Trial of medicinal product or medical device *Please consult* [*TCD Sponsor*](https://www.tcd.ie/research/support/sponsorship.php) *for details on registration, ethical and other regulatory requirements for trials of this nature. Note that some medical apps may fall under the medical device regulations. If this intervention type is selected, a letter of compliance from the Head of Clinical Sponsorship Oversight (HSCO) will be required as an appendix to this application. Please contact* [*clinicaltrialsponsorship@tcd.ie*](mailto:clinicaltrialsponsorship@tcd.ie)*.* |
|  | 4. Educational |
|  | 5. Other – please state below |

**2.4.6** Please identify classification of OTHER intervention type (if applicable).

|  |
| --- |
|  |

**2.4.7** (b) Outline the intervention.

*Clearly indicate in your outline if this is a new intervention that is being developed and tested (both trial and non-trial projects) or a non-trial evaluation of a practice that is already in place.*

|  |
| --- |
|  |

**2.4.8 What is the approximate size of the target population?** *REAMS interface requires a SINGLE NUMBER to be entered here. If this requires clarification/explanation (e.g. you have different populations for different elements of your project), please address this in the text box for 2.4.10 below.*

|  |
| --- |
|  |

**2.4.9 What is the proposed sample size, *i.e.* how many participants are to be involved in the study?** *REAMS interface requires a SINGLE NUMBER to be entered here. If this requires clarification/explanation (e.g. you will be undertaking interviews until data saturation), please address this in the text box for 2.4.10 below.*

|  |
| --- |
|  |

**2.4.10 What is the justification for this sample size?**

|  |
| --- |
|  |

**2.4.11 Outline the method of analysis.** *(Word limit = 100 words.)*

|  |
| --- |
|  |

**3. ANIMAL RESEARCH**

Section 3 relates to Animal Research and is not included in this Word file.

**4. RISKS, BENEFITS, CONFIDENTIALITY AND CONFLICT**

**The RISKS, BENEFITS, CONFIDENTIALITY AND CONFLICT section (all subsections) must be completed for all projects.**

**4.1 RISK OR HARM TO THE RESEARCHER**

**4.1.1 What setting(s) will be used for data collection?** *Choose all that apply.  
Please note the* [*University Lone Working Policy and Guidance*](https://www.tcd.ie/about/policies/Trinity%20College%20Lone%20Working%20Policy.%20Rev.%201.0.Board%20Approved.pdf)*.*

|  |  |  |  |
| --- | --- | --- | --- |
|  | 1. Place of convenience for participants |  | 6. Laboratory |
|  | 2. Participants' place of work |  | 7. In a foreign country |
|  | 3. Participants' home |  | 8. Online |
|  | 4. Classroom |  | 9. None |
|  | 5. Hospital/clinic |  |  |

4.1.2 Other (please elaborate)

|  |
| --- |
|  |

Researcher Risk  
*Here you must d*escribe the potential risk(s), if any, to the researcher(s) and your plan(s) for mitigation.   
*Please include all potential risks to the researcher(s), even if the chance of occurrence is low. If no risks to the researcher(s) have been identified, indicate 'None' in the first row (4.1.3) and leave the remaining rows (4.1.4-4.1.7) blank. Copy and paste the table (4.1.3-4.1.7) as many times as required – one table for each individual risk you have identified.*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 4.1.3 Identify the risk category from (a)-(e) below.   |  | | --- | | (a) The topic explored is potentially intrusive/harmful or may potentially endanger the researcher | | (b) Emotional risks including stress, distress or discomfort | | (c) Physical risks including bodily harm, aggression or violence | | (d) Other | | (e) None |   *If NONE, please leave 4.1.4 to 4.1.7 blank.* |  |
| 4.1.4 If OTHER, please specify |  |
| 4.1.5 Estimate the impact Low/Medium/High *(Worst case scenario)* |  |
| 4.1.6 Estimate the probability/likelihood Low/Medium/High |  |
| 4.1.7 Detail the mitigation measure(s) *4.1.3 only categorizes the risk. Therefore please also provide a brief description of the risk here, as well as outlining its mitigation.* |  |

4.1.8 Are you a School of Psychology applicant interviewing or testing with adults or children?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

*If YES, the* TCD School of Psychology Guidelines for Interviewing or Testing Adults *(signed declaration) must be appended to this application.*   
*See Appendix 2 of the* [*Guidance Document*](https://www.tcd.ie/research/support/assets/pdf/REAMs%20Making%20An%20Application%20Manual%2018.12.23%20.pdf)*.*

**4.2 RISK OR HARM TO SITE, ENVIRONMENT OR SOCIETY**

Site/Environment/Society Risk  
*Here you must describe the potential risk(s), if any, to the data collection site (including confidentiality of site), environment or society, and your plan(s) for mitigation.   
Please include all potential risks, even if the chance of occurrence is low. If no risks have been identified, indicate 'None' in the first row (4.2.1) and leave the remaining rows (4.2.2-4.2.4) blank. Copy and paste the table (4.2.1-4.2.4) as many times as required – one table for each individual risk you have identified.*

|  |  |  |  |
| --- | --- | --- | --- |
| 4.2.1 Identify the risk category from (a)-(b) below.   |  | | --- | | (a) Risk to environment, site or society | | (b) None |   *If NONE, please leave 4.2.2 to 4.2.4 blank.* |  |
| 4.2.2 Estimate the impact Low/Medium/High *(Worst case scenario)* |  |
| 4.2.3 Estimate the probability/likelihood Low/Medium/High |  |
| 4.2.4 Detail the mitigation measure(s) *4.2.1 only categorizes the risk. Therefore please also provide a brief description of the risk here, as well as outlining its mitigation.* |  |

**4.3 RISK OR HARM TO PARTICIPANTS**

4.3.1 Does any member of the research team have a dependent relationship with the participants?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

**4.3.2** If YES, detail the role of the researcher(s) in the project, the relationship of the researcher(s) with the participants normally, and how you will mitigate against coercion of participants to participate in the project and/or influencing their responses.

|  |
| --- |
|  |

Participant Risk  
*Here you must d*escribe the potential risk(s), if any, to the participants and your plan(s) for mitigation.   
*Please include all potential risks to the participants, even if the chance of occurrence is low. If no risks to the participants have been identified, indicate 'None' in the first row (4.3.3) and leave the remaining rows (4.3.4-4.3.7) blank. Copy and paste the table (4.3.3-4.3.7) as many times as required – one table for each individual risk you have identified.*

*Note that the risks you cite here, and the mitigations proposed, should be incorporated into the PIL, in order that they may be brought to the attention of prospective participants.*

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 4.3.3 Identify the risk category from (a)-(j) below.   |  | | --- | | (a) Inconvenience | | (b) Physical risks | | (c) Emotional risks, including stress, distress or discomfort | | (d) Reputational risks | | (e) Financial risks, including exposure or loss | | (f) Loss of privacy | | (g) The topic explored is potentially intrusive | | (h) The research may be harmful or may potentially endanger participants | | (i) Other | | (j) None |   *If NONE, please leave 4.3.4 to 4.3.7 blank.* |  |
| 4.3.4 If OTHER, please specify |  |
| 4.3.5 Estimate the impact Low/Medium/High *(Worst case scenario)* |  |
| 4.3.6 Estimate the probability/likelihood Low/Medium/High |  |
| 4.3.7 Detail the mitigation measure(s) *4.3.3 only categorizes the risk. Therefore please also provide a brief description of the risk here, as well as outlining its mitigation.* |  |

**4.4 PARTICIPANT BENEFITS AND CONFIDENTIALITY**

4.4.1 Is it foreseeable that participants could potentially reveal information that you have a legal obligation to disclose (*e.g*. child protection policy, malpractice, *etc*.)?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

**4.4.2** If YES, what information may be disclosed, why, and to whom?

|  |
| --- |
|  |

**4.4.3 Outline any direct benefits to research participants of participation.**

|  |
| --- |
|  |

**4.5 CONFLICT OF INTEREST (arising from personnel)**

4.5.1 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?

*Conflicts of Interest arising from project funding will be dealt with separately and should NOT be entered here. (See Section 6.2.)*

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

**4.5.2** If YES, give details of the conflict of interest and what mitigation measures are in place.

|  |
| --- |
|  |

**5. HUMAN BIOLOGICAL SAMPLES**

**The HUMAN BIOLOGICAL SAMPLES section must be completed if the project involves any of the following (see 2.1.13):**

* **Human biological samples that are not from patients, and that have been taken in a non-intrusive manner;**
* **Human biological samples from patients;**
* **Human biological samples taken in an invasive manner;**
* **Human biological samples of any size or type that could have an impact on future treatment (*e.g*. human DNA sequencing).**

*If not applicable, use the grey highlighter in Word to shade this component.*

*Please ensure that the information you provide in this section is consistent with your responses in the methodology section of this application form (Section 2.4) and any relevant appendices, including your materials for participants.*

**5.1 HUMAN BIOLOGICAL SAMPLES**

**5.1.1 Will the samples in any form be stored for any period after the project’s completion?**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Yes |  | No | No |

If YES:

**5.1.2 State what type of samples will be stored.**

|  |
| --- |
|  |

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

|  |
| --- |
|  |

**5.1.4 Planned date(s) of destruction of samples.**

|  |
| --- |
|  |

**5.1.5 Does the project involve the use of genetic data?**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

**6. FUNDING**

**The FUNDING section (all subsections) must be completed for all projects that are funded (see 2.1.14).**

**6.1 FUNDING DETAILS**

**6.1.1 Insert TCD Research Proposal and Awards Management System (RPAMS) number if applicable and available.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | RPAMS number |  | Not available |  | Not applicable |

**6.1.2 Outline sources of funding: List names of all confirmed sources of funding or support (including in-kind benefit), and for each state if it is industry/commercial, state/public, philanthropic/charitable or other.** *Add as many rows as required (one row per funding source).*

|  |  |
| --- | --- |
| ***Funding source*** | ***Funding type*** |
|  |  |
|  |  |

**6.1.3 Please specify any funder specific requirements or obligations which should be brought to the attention of the Research Ethics Committee and/or Trinity Research & Innovation.**

|  |
| --- |
|  |

**6.1.4 Will the results of the project be used or disclosed for commercial purposes?**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

**6.1.5 Please clarify which party/parties shall have the commercialisation and/or intellectual property rights.**

|  |
| --- |
|  |

**6.2 CONFLICT OF INTEREST (arising from funding or commercialisation)**

**6.2.1 Are you aware of any possible conflict of interest arising from the funding or commercialisation of this project?**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

**6.2.2** If YES, give details of the conflict of interest and what mitigation measures are in place.

|  |
| --- |
|  |

**6.2.3 Is there likely to be possible conflict of interest between the funders of the project and the aims and/or results of the project?**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

**6.2.4** If YES, give details of the conflict of interest and what mitigation measures are in place.

|  |
| --- |
|  |

**7. SAMPLING AND RECRUITMENT**

**The SAMPLING AND RECRUITMENT section must be completed if data are to be collected from primary sources (whether or not secondary sources are also used). (See 2.2.3.)**

**7.1 SAMPLING AND RECRUITMENT**

**7.1.1 Outline the sampling method.**

|  |
| --- |
|  |

**7.1.2 Describe the time commitment of a participant.**

|  |
| --- |
|  |

7.1.3 Will the research require/use a gatekeeper?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If YES, complete 7.1.4 to 7.1.7 below.

|  |
| --- |
| **7.1.4 Outline the position/role of the gatekeeper within the organisation.** |
| **7.1.5 Detail the role of the gatekeeper in the project.** |
| **7.1.6 Is there a dependent relationship between the gatekeeper and the participants?**   |  |  |  |  | | --- | --- | --- | --- | |  | Yes |  | No |   **7.1.7** If YES, outline how this is going to be managed to mitigate against the dependencies.   |  | | --- | |  | |

**7.1.8 Give a detailed step by step description of how participants will be recruited and append the recruitment material.** *(Word limit: 100 words)   
The recruitment material to be appended includes any posters, flyers, advertisements, website/social media notifications, letters/emails of invitation to prospective participants (including cover letters) and participant information leaflets (PILs).*

|  |
| --- |
|  |

**8. CONSENT**

**The CONSENT section must be completed if you will obtain consent/assent from participants (see 2.2.4).**

**8.1 CONSENT**

**8.1.1 How will consent be obtained, and by whom?**

|  |
| --- |
|  |

8.1.2 Do your participants require support to give consent?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

**8.1.3** If YES, provide further information.

|  |
| --- |
|  |

8.1.4 Do you require assent from participants, (*e.g*. because of their vulnerability)?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If YES, complete 8.1.5-8.1.6 below.

|  |
| --- |
| **8.1.5 How will assent be obtained and by whom?** |
| **8.1.6 Provide further information.** *E.g. further information on the need for assent or any further information* relevant to the assent process. |

8.1.7 Are you required to have Garda vetting? *E.g. researchers who undertake research in which they will come in contact with children must undergo Garda vetting. It may also be required in certain health settings.*

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

*If YES, confirmation of satisfactory up-to-date Garda vetting should be appended.*

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

|  |  |  |  |
| --- | --- | --- | --- |
|  | Less than 7 days |  | 7 or more days |

**8.1.9** If LESS THAN 7 DAYS, provide further information.

|  |
| --- |
|  |

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

|  |
| --- |
|  |

**8.1.11 Describe how participants can withdraw their consent and/or their data.** *If there is a timepoint beyond which withdrawal is no longer possible, this should be identified.*

|  |
| --- |
|  |

**9. HEALTH RESEARCH**

**The HEALTH RESEARCH section must be completed if the project is health research as defined by the Health Research Regulations (see 2.2.8).**

*HRB guidance on Health Research Regulations 2018:* [*https://www.hrb.ie/funding/gdpr-guidance-for-researchers/health-research-regulations-2018/*](https://www.hrb.ie/funding/gdpr-guidance-for-researchers/health-research-regulations-2018/) *HRCDC guidance on amendments to the Health Research Regulations:* [*https://hrcdc.ie/guidance/*](https://hrcdc.ie/guidance/)

*Health research generally requires explicit consent unless the conditions for an exception are met.*

**9.1 HEALTH RESEARCH**

**9.1.1 Please indicate which of the following apply to your health research project.** *Choose all that apply.*

|  |  |
| --- | --- |
|  | 1. Explicit consent will be obtained. *Consent form must be appended.* |
|  | 2. The data are irreversibly anonymized. |
|  | 3. You are carrying out a low risk, retrospective chart review. *Confirmation that the required criteria have been met, including a copy of the public notice and local site DPO approval, must be appended.  See* [*https://hrcdc.ie/wp-content/uploads/2021/01/3.-Guidance-on-Retrospective-Chart-Review-Amendments-Jan-2021.pdf*](https://hrcdc.ie/wp-content/uploads/2021/01/3.-Guidance-on-Retrospective-Chart-Review-Amendments-Jan-2021.pdf)*.* |
|  | 4. Deferred consent. *Consent form must be appended.* |
|  | 5. You obtained informed consent prior to 08 August 2018. *Consent form must be appended.* |
|  | 6. A consent declaration has been/will be obtained from the Health Research Consent Declaration Committee. *Completed HRCDC application form must be appended.  The DPO must be consulted when completing this application form.* |

**9.1.2 Only required if an intervention is part of the project protocol (2.2.4).****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 |

**9.1.3 Will the project involve the administration of any substance(s) or require participants to refrain from taking any substance(s)?**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

**9.1.4** If YES, please detail each substance, amount, desired effect, possible side effects and measures for minimising risk.

|  |
| --- |
|  |

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

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

**9.1.6 Will the research participants' general practitioners (GPs) be informed that they are taking part in the project?** *If the project gives participants the choice of whether or not their GP will be informed, answer YES to this question.*

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

**9.1.7 Will permission be sought from the research participants to disclose information (for example, information about adverse outcomes) to their GPs?**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Yes |  |  | No |

**10. DATA PROTECTION**

**10.1 OPENING QUESTIONS**

**The OPENING QUESTIONS are required if the project data can identify participants, either directly or indirectly.***If not applicable, use the grey highlighter in Word to shade this component.*

**10.1.1 Have all Trinity researchers (staff and students) in this project completed the College Data Protection GDPR training module?***See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.1.1.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.1.1.pdf)*.  
See also details of GDPR training module at:* [*https://www.tcd.ie/itservices/vle/kb/overview-GDPRtraining.php*](https://www.tcd.ie/itservices/vle/kb/overview-GDPRtraining.php)*. Foe PhD students, completion of* [*CA7000: Research Integrity and Impact in an Open Scholarship Era*](https://www.tcd.ie/dataprotection/training/) *fulfils this requirement.*

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

**10.1.2 Are all Trinity staff and Trinity students familiar with the Trinity College Personal Data Breach Procedural Guidelines?** The *University Personal Data Breach Procedural Guidelines are linked on the following webpage:* [*https://www.tcd.ie/dataprotection/databreach/*](https://www.tcd.ie/dataprotection/databreach/). *Review these procedural guidelines before answering. Application cannot procced unless the answer to the question is 'Yes'. Further guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.1.2.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.1.2.pdf)

|  |  |
| --- | --- |
|  | Yes |

**10.2 DATA PROTECTION INFORMATION**

**The DATA PROTECTION INFORMATION subsection is required if the project data can identify participants, either directly or indirectly.***If not applicable, use the grey highlighter in Word to shade this component.*

*Trinity as an organization may be the data controller or data processor depending on staff and students’ roles in the project. In this subsection you will need to detail how information is shared within Trinity, with external third parties and with parties outside the EEA/EU as applicable.*

**10.2.1 What is/are Trinity's role(s) in the project?***See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.1.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.1.pdf)*.   
If the data controller role is shared, the joint data controller agreement(s) with the other organization(s) must be appended.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Data controller (sole controller) |  | Joint data controller |  | Data processor |

**10.2.2 How many participants' personal data are being processed in this project?***See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.2.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.2.pdf)*.*

|  |  |  |  |
| --- | --- | --- | --- |
|  | < 100 |  | > 100 |

*A response of “> 100” indicates that a DPO review must be undertaken, using the* [*data protection review template*](https://www.tcd.ie/dataprotection/assets/docs/reviewtemplate/202309_DP_Review_template.docx)*. You should email the completed template to* [*dataprotection@tcd.ie*](mailto:dataprotection@tcd.ie) *along with data protection training certificate(s) for the research team member(s), using the email subject line “data protection review”, and await instructions and feedback from the DPO (who may require further documentation) in order to obtain a DPO Review Letter of Completion. If the response to this question is “> 100”, it will be necessary to include the DPO Review Letter of Completion as an appendix to this application form. You cannot submit your application to the REC until this letter has been received from the DPO and appended.*

**10.2.3 List all types of personal data (including any special category or sensitive personal data) that you will process during the lifecycle of the project.***See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.3.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.3.pdf)*.*

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**10.2.4 Does the project involve processing of special category data or data relating to criminal convictions and/or offences (sensitive personal data)?***Please consult the guidance before answering this question so you fully understand the scope of the data in question:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.4.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.4.pdf)*. Note that ‘special category data’ includes health data.*

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

*YES indicates that a DPO review must be undertaken, using the* [*data protection review template*](https://www.tcd.ie/dataprotection/assets/docs/reviewtemplate/202309_DP_Review_template.docx)*. You should email the completed template to* [*dataprotection@tcd.ie*](mailto:dataprotection@tcd.ie) *along with data protection training certificate(s) for the research team member(s), using the email subject line “data protection review”, and await instructions and feedback from the DPO (who may require further documentation) in order to obtain a DPO Review Letter of Completion. If the response to this question is YES, it will be necessary to include the DPO Review Letter of Completion as an appendix to this application form. You cannot submit your application to the REC until this letter has been received from the DPO and appended.*

**10.2.5 Are the personal data shared outside the research team with any other unit(s) within Trinity College?***See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.5.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.5.pdf)*.*

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

**10.2.6** If YES, name the unit(s) with which data are shared. Detail what personal data should be shared with them and why.  
*See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.6.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.6.pdf)*.*

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**10.2.7 Are the personal data shared with any third party/parties outside Trinity?***See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.7.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.7.pdf)*.*

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If YES:

**10.2.8** Provide the names of these organisations, and detail what personal data will be shared with them and why. *Add as many rows as required.  
See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.8.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.8.pdf)*.*

|  |  |  |
| --- | --- | --- |
| ***Organization*** | ***Personal data shared*** | ***Reason*** |
|  |  |  |
|  |  |  |

**10.2.9** Describe what IT due diligence you intend to carry out or have carried out on these organisations.  
*See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.9.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.9.pdf)*.*

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**10.2.10 Provide a general description of the security measures in place to keep project data secure for each system, platform and application you will use for access, storage, and transfer, including but not limited to: multi-factor authentication, use of passwords, use of a virtual private network (VPN), device encryption, vendor ISO certification, anti-virus used, use of secure file transfers such as HEAnet, details of how data are backed up *etc*.***See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.10.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.10.pdf)*.*

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**10.2.11 Are the data transferred outside the UK & EEA?***See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.11.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.11.pdf)*.*

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

*If YES, you must contact the Data Protection Office.*

**10.2.12 Detail how long personal data will be retained in an identifiable or coded format.***See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.12.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.2.12.pdf)*.*

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**10.3 PROCESSING RISK**

**The PROCESSING RISK subsection is required if personal data are being processed.**

*Here you must describe the potential data processing risk(s), if any, and your plan(s) for mitigation.   
Please include all potential risks, even if the chance of occurrence is low. If no risks have been identified, indicate 'None' in the first row (10.3.1) and leave the remaining rows (10.3.2-10.3.4) blank. Copy and paste the table (10.3.1-10.3.4) as many times as required – one table for each individual risk you have identified.*

*See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.5.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.5.pdf)*.*

|  |  |
| --- | --- |
| 10.3.1 State the processing risk of any kind  *If NONE, state this here, and leave 10.3.2 to 10.3.4 blank.* |  |
| 10.3.2 Estimate the severity/impact Low/Medium/High *(Worst case scenario)* |  |
| 10.3.3 Estimate the probability/likelihood Low/Medium/High |  |
| 10.3.4 Detail the solution(s)/mitigation measure(s) |  |

**10.4 CLOSING SECTION**

**This CLOSING SECTION is optional.**

**10.4.1 Include any additional information in respect of the study that may be relevant.**

|  |
| --- |
|  |

**11. ATTACHMENTS**

REAMS will automatically prompt applicants for several attachments (listed in a pink box on REAMS), and will block submission of the application until all the listed attachments have been uploaded. Mandatory attachments will disappear from the pink box as they are uploaded.

For each attachment, you will need to complete three data fields:

11.1.1 File name

11.1.2 File description

11.1.3 Document type. A dropdown list is available here. If your document type is not listed, there is an option to choose “other documentation”.

A fourth data field (11.1.4) will only need to be completed for some attachments, namely where the document being uploaded is associated with a particular person, site or item (*e.g.* a data protection training certificate for specific member of the research team). In REAMS, the pink box listing outstanding attachments may indicate in parentheses the person/site/item with whom or with which it should be associated. When uploading, the association can be made by choosing the relevant person/site/item from a dropdown menu.

The attachments required will vary from project to project, but are likely to include many on the list below. Throughout this application form, there have been some prompts **in green** indicating requirements for certain documentation. You should ensure that all those indicated for your project have been gathered in readiness for your application. It is possible to upload additional attachments besides those mandated by REAMS, so you should submit any others that you consider relevant to your application.

Note that the table below is not an exhaustive list. Your project may require other attachments besides those shown here, and if so, you should identify these in the section for ‘other documentation’.

**Please use meaningful file names for your attachments. All appendices should be numbered, and when referring to appendices in the body of your application form, the cross-reference should include the appendix number.**

In the table below, please consider each entry carefully and indicate the relevant appendix number(s) or mark the entry as not applicable to your project.

| **Index of appendices** | **Appendix number(s)**  ***Mark N/A if not applicable*** |
| --- | --- |
| **Research team (applicant and collaborator(s)** | |
| Data protection training certificate(s), **dated within the last 24 months**  *TCD* [*data protection training module*](https://www.tcd.ie/itservices/vle/kb/overview-GDPRtraining.php) *is required for:*   * *All applicants (all projects)* * *All primary supervisors (all projects)* * *All TCD collaborators if the project includes the processing of personal data*   *For Ph.D. students, the certificate for CA7000: Research Integrity and Impact in an Open Scholarship Era fulfils this requirement* |  |
| Research integrity module certification All Ph.D. students in the research team must have completed module [CA7000: Research Integrity and Impact in an Open Scholarship Era](https://www.tcd.ie/dataprotection/training/) and append certification.  * For non-Ph.D. students and staff, [Epigeum Research Integrity training](https://www.tcd.ie/research/support/epigeum.php) is available (not mandatory). If any members of the research team have completed it, they should append certification. |  |
| Garda vetting clearance documentation (up to date) |  |
| **Project details** | |
| Dual use research management plan |  |
| **Access to sites/resources:** | |
| Letter(s)/email(s) seeking access to study sites/resources/support and response(s) confirming that access will be provided  *E.g. agreement from institution(s)/organisation(s) agreeing to host the research project, assist with participant recruitment (e.g. publicise the study or act as a gatekeeper), facilitate access to data etc.* |  |
| Licence to access site/source |  |
| Approval from Research Ethics Committee or other relevant committee (*e.g.* Clinical Audit Committee) at external site(s) |  |
| Trinity staff access permissions *See* [*https://www.tcd.ie/Communications/internal-communications/email-protocol/*](https://www.tcd.ie/Communications/internal-communications/email-protocol/) |  |
| Trinity students access permissions  *See* [*https://www.tcd.ie/Communications/internal-communications/email-protocol/*](https://www.tcd.ie/Communications/internal-communications/email-protocol/)*. Depending on target student population and mechanism by which they are reached, other permission(s) may also be required, e.g. from Head of School, Faculty Dean, Director of Research, Director of UG or PG programmes.* |  |
| **Sampling and recruitment** |  |
| Recruitment poster(s), flyer(s), advertisement(s), website/social media notification(s) |  |
| Letter(s)/email(s) of invitation to prospective participants (including cover letters) |  |
| Participant information leaflet(s)  *Only required if you are recruiting participants. It is essential that the details in the PIL(s) are consistent with the details in the application form. Note the three possible PIL templates depending on the research type:*   * *PIL where personal data are not being processed:  See template in Appendix 1 of* [*TCD Guidance on Making an Application*](https://www.tcd.ie/research/support/assets/pdf/Top%20Guidance_Simplified-31st%20Oct.pdf) * *PIL for health research in which personal data are processed:  See* [*https://www.tcd.ie/dataprotection/trinitycollegetemplates/*](https://www.tcd.ie/dataprotection/trinitycollegetemplates/) * *PIL for non-health research in which personal data are processed:  See* [*https://www.tcd.ie/dataprotection/trinitycollegetemplates/*](https://www.tcd.ie/dataprotection/trinitycollegetemplates/) |  |
| **Consent/assent** |  |
| Informed consent form(s) (ICF) for participants with capacity to give consent *Note that explicit consent is required for health research. TCD has separate ICF templates for health research and non-health research. See* [*https://www.tcd.ie/dataprotection/trinitycollegetemplates/*](https://www.tcd.ie/dataprotection/trinitycollegetemplates/). |  |
| ICF for proxy consent given on a participant’s behalf by another individual who is authorized to act on their behalf, with assent by a participant who is competent to give assent |  |
| Completed HRCDC consent declaration application form.  *Required if relying on a consent declaration. See* [*https://hrcdc.ie/apply/*](https://hrcdc.ie/apply/)*.Note that any application to the Health Research Consent Declaration Committee for a consent declaration must be carried out in consultation with TCD's Data Protection Officer* |  |
| Public notice(s) at study site(s) if not seeking consent for retrospective chart/patient record review. *See* [*https://hrcdc.ie/wp-content/uploads/2021/01/3.-Guidance-on-Retrospective-Chart-Review-Amendments-Jan-2021.pdf*](https://hrcdc.ie/wp-content/uploads/2021/01/3.-Guidance-on-Retrospective-Chart-Review-Amendments-Jan-2021.pdf)*.* |  |
| **Data collection tool(s)** |  |
| Questionnaire |  |
| Interview guide |  |
| Observation schedule |  |
| Data extraction form |  |
| Other data collection tool(s) |  |
| **Risks, benefits, confidentiality and conflict** |  |
| TCD School of Psychology Guidelines for Interviewing or Testing Adults (signed declaration)*.* *See Appendix 2 of* [*TCD Guidance on Making an Application*](https://www.tcd.ie/research/support/assets/pdf/Top%20Guidance_Simplified-31st%20Oct.pdf)*.* |  |
| **Data protection** |  |
| DPO review – letter of completion |  |
| DPIA(s) for external site(s), if required by external site(s)  *Note that TCD’s DPIA and DPRA will be managed separately via the Data Protection Review process.* |  |
| Joint data controller agreement |  |
| Data processor agreement *(E.g. contract with transcription service containing appropriate non-disclosure/data protection clauses)* |  |
| Local site DPO approval if not seeking consent for retrospective chart/patient record review |  |
| **Other documentation (please specify)** |  |
|  |  |

**DECLARATIONS**

**Signature and final page (Applicant's declaration)**

**Required for all applications**

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Yes** | **Signature** |  | **Date** |  |

**Principal investigator's declaration**

**Required if applicant is not the principal investigator.***If not applicable, use the grey highlighter in Word to shade this component.*

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Yes** | **Signature** |  | **Date** |  |

**Supervisor's declaration**

**Required if applicant is a student.***If not applicable, use the grey highlighter in Word to shade this component.*

* 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.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Yes** | **Signature** |  | **Date** |  |