**School of Dental Science Level 2 Research Ethics Committee (REC)**

**RESEARCH ETHICS APPLICATION FORM**

**CONFIDENTIAL**

|  |
| --- |
| * Before submitting an application, please read the [TCD Policy on Good Research Practice](https://www.tcd.ie/research/assets/pdf/Policy%20on%20Good%20Research%20Practice_June2021.pdf).
* **This application form is only for use by students undertaking postgraduate taught programmes and undergraduate programmes.** Staff and research postgraduates should use the REAMS online system.
* The form is designed to be completed with reference to the relevant College guidance. In particular, you should consult:
* [TCD guidance on the background to making an ethics application](https://www.tcd.ie/research/support/assets/pdf/Top%20Guidance_Background%2031st%20Oct.pdf) (labelled for REAMS but also includes information relevant to email applications, including information on risk levels and eligibility for review by Level 2 or Level 3 RECs).
* [TCD guidance on completion of the application form](https://www.tcd.ie/research/support/assets/pdf/Top%20Guidance_Simplified-31st%20Oct.pdf) (labelled for REAMS but also includes information relevant to email applications). **This includes a question by question guide to interpretation and completion of the form. You are strongly encouraged to consult this as you work on your application.** Note that for the data protection components there are separate links to question by question guidance within the form.
* [TCD templates](https://www.tcd.ie/dataprotection/trinitycollegetemplates/) for participant information leaflets and consent forms.

Some core guidance and links are provided ***in blue font*** throughout this application form.* Some sections/questions must be completed for all projects, while others are only required for a subset of projects. Please read the application form carefully to identify the questions that are relevant to your project. If you believe that a section/subsection/question is not relevant to your project, you should not delete it from the form but instead should use the highlighter function in Word to shade it in grey, like this. In this way it will be easy for you and reviewers to skip past questions that do not require completion, yet if it later becomes apparent that an omitted question needs to be answered, it remains available and the grey shading can be removed.
* **The TCD Data Protection Risk Assessment (DPRA) and TCD Data Protection Impact Assessment (DPIA) are built into this application form** for completion where applicable; separate forms are not required. (However, if an external site required a DPIA for this project, that DPIA should be appended.)
* This application form and numbered appendices for project documentation (certificates, letters of permission, recruitment material, cover letter, participant information leaflet, consent form, data collection tools *etc.*) **must be combined into a single Microsoft Word or pdf file** and emailed to gpmoran@dental.tcd.ie Student applicants should copy their supervisor on the application email.
* Incomplete applications (including applications with incomplete checklists or which lack the required signatures) will not be reviewed.
* The application and approval process is electronic; a hard copy of the application documentation is not required.
* Note that all applicants must submit an annual report for ongoing projects and an end of project report upon completion of the study.
* **This application is for ethics approval only. It is the project team’s responsibility to ensure that all legal, clinical, administrative and professional requirements are met, including compliance with data protection legislation, health and safety legislation and TCD policies.** Data protection in TCD: <https://www.tcd.ie/dataprotection/>TCD policies: <https://www.tcd.ie/about/policies/>
 |

**Index**

The body of this application form contains the following sections:

|  |  |
| --- | --- |
| **SECTION** | **STATUS***Note that within mandatory sections there may be some questions that do not apply to all applications* |
| **TEAM** | **Applicant and collaborators** | Mandatory for all applications |
|  | TEAM.A Applicant details |
|  | TEAM.B Trinity collaborators |
|  | TEAM.C Non-Trinity collaborators |
| **PROJ** | **Project overview** | Mandatory for all applications |
|  | PROJ.A Main project details |
|  | PROJ.B Details on human data and collection |
|  | PROJ.C Research sites and data sources |
|  | PROJ.D Outline of project methods |
| **SMPL** | **Sampling and recruitment** | Required if project data are to be collected from primary sources |
| **HLTH** | **Health research** | Required if the project is Health Research as defined in the Health Research Regulations |
| **CONS** | **Consent** | Required if the project requires consent or assent from participants |
| **RISK** | **Risks, benefits, confidentiality and conflict** | Mandatory for all applications |
|  | RISK.A Risk or harm to researcher |
|  | RISK.B Risk or harm to site, environment or society |
|  | RISK.C Risk or harm to participants |
|  | RISK.D Participant benefits and confidentiality |
|  | RISK.E Conflict of interest (personnel) |
| **FUND** | **Funding and conflict of interest** | Required if the project is funded |
|  | FUND.A Funding |
|  | FUND.B Conflict of interest (funding) |
| **BIOL** | **Human biological samples** | Required if the project utilizes human biological samples |
| **DATA** | **Data protection** | Required if the data being processed could directly or indirectly identify a living individual |
|  | DATA.A Opening questions |
|  | DATA.B Data protection assessment |
|  | DATA.C Data protection risk assessment (DPRA) |
|  | DATA.D Data protection impact assessment (DPIA) |
|  | DATA.E Processing risk |
|  | DATA.F Closing section |
| **DECL** | **Declarations** | Mandatory for all applications |
|  | DECL.A Applicant declaration |
|  | DECL.B Principal investigator (PI) declaration |
|  | DECL.C Supervisor declaration |
| **APP** | **Appendices** | Index (checklist) is mandatory for all applications. The appendices will vary depending on the project. |

It is likely that you will need to append additional material to your application. Some examples (non-exhaustive) are indicated **in green** throughout the application form. The appendices required will depend on the nature of your project. You must combine all material into **a single Word or pdf file** prior to submission.

**TEAM. APPLICANT AND COLLABORATORS**

**TEAM.A APPLICANT DETAILS**

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

|  |  |  |
| --- | --- | --- |
| **TEAM.A.1 Applicant name** *(Title, Given name, FAMILY NAME)* |  | **TEAM.A.2 Are you applying as a member of staff or a student?** |
|  |  |  | Staff |  | Student |
| **TEAM.A.3 Staff / Student number** |  | **TEAM.A.4 Email address** |
|  |  |  |
| **TEAM.A.5 School / Department** |  | **TEAM.A.6 Role on the project** |
|  |  |  | Principal investigator |  | Investigator (non-PI) |  | Other |
| **TEAM.A.7 Primary employer (if not Trinity)** |  | **TEAM.A.8 Other affiliations (if applicable)** |
|  |  |  |
| **TEAM.A.9 Course (for student applicant only)** |  | **TEAM.A.10 Part time / full time** |
|  | PhD |  |  | Part-time |
|  | Professional doctorate |  |  | Full-time |
|  | Masters by research |  |  |  |
|  | Taught masters |  |  |  |
|  | Undergraduate |  |  |  |

**TEAM.A.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/research/assets/pdf/Policy%20on%20Good%20Research%20Practice_June2021.pdf)*.*

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

**TEAM.A.12 I have completed a 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.
See link:* [*Epigeum research integrity training (staff and other students)*](https://www.tcd.ie/research/support/epigeum.php)*. AVAILABLE.*

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

**TEAM.A.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 |

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

*Collaborators are members of the research team. Copy and paste the subsection below (TEAM.B.1-5) 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).*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TEAM.B.1 Role(s) on the project** |  | TCD principal investigator |  | Stakeholder (academic) |
|  | Primary supervisor |  | Stakeholder (clinical) |
|  | Co-supervisor |  | Stakeholder (professional) |
|  | Collaborator |  | Stakeholder (industrial) |
| **TEAM.B.2 Name** *(Title, Given name, FAMILY NAME)* |  |
| **TEAM.B.3 Email address** |  |
| **TEAM.B.4 TCD affiliation (*e.g.* School/ Department /Centre)**  |  |
| **TEAM.B.5 Job title/role within TCD** |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TEAM.B.1 Role(s) on the project** |  | TCD principal investigator |  | Stakeholder (academic) |
|  | Primary supervisor |  | Stakeholder (clinical) |
|  | Co-supervisor |  | Stakeholder (professional) |
|  | Collaborator |  | Stakeholder (industrial) |
| **TEAM.B.2 Name** *(Title, Given name, FAMILY NAME)* |  |
| **TEAM.B.3 Email address** |  |
| **TEAM.B.4 TCD affiliation (*e.g.* School/ Department /Centre)**  |  |
| **TEAM.B.5 Job title/role within TCD** |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TEAM.B.1 Role(s) on the project** |  | TCD principal investigator |  | Stakeholder (academic) |
|  | Primary supervisor |  | Stakeholder (clinical) |
|  | Co-supervisor |  | Stakeholder (professional) |
|  | Collaborator |  | Stakeholder (industrial) |
| **TEAM.B.2 Name** *(Title, Given name, FAMILY NAME)* |  |
| **TEAM.B.3 Email address** |  |
| **TEAM.B.4 TCD affiliation (*e.g.* School/ Department /Centre)**  |  |
| **TEAM.B.5 Job title/role within TCD** |  |

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

*Collaborators are members of the research team. Copy and paste the subsection below (TEAM.C.1-6) as many times as required for completion by each non-TCD collaborator.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TEAM.C.1 Role(s) on the project** |  | Non-TCD principal investigator |  | Stakeholder (academic) |
|  | Non-TCD co-supervisor |  | Stakeholder (clinical) |
|  | Collaborator |  | Stakeholder (professional) |
|  | Public/patient/participant collaborator |  | Stakeholder (industrial) |
| **TEAM.C.2 Name** *(Title, Given name, FAMILY NAME)* |  |
| **TEAM.C.3 Email address** |  |
| **TEAM.C.4 Primary/relevant non-TCD affiliation (name of organization)** |  |
| **TEAM.C.5 Job title/role within non-TCD organization** |  |
| **TEAM.C.6 Country/countries** |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TEAM.C.1 Role(s) on the project** |  | Non-TCD principal investigator |  | Stakeholder (academic) |
|  | Non-TCD co-supervisor |  | Stakeholder (clinical) |
|  | Collaborator |  | Stakeholder (professional) |
|  | Public/patient/participant collaborator |  | Stakeholder (industrial) |
| **TEAM.C.2 Name** *(Title, Given name, FAMILY NAME)* |  |
| **TEAM.C.3 Email address** |  |
| **TEAM.C.4 Primary/relevant non-TCD affiliation (name of organization)** |  |
| **TEAM.C.5 Job title/role within non-TCD organization** |  |
| **TEAM.C.6 Country/countries** |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TEAM.C.1 Role(s) on the project** |  | Non-TCD principal investigator |  | Stakeholder (academic) |
|  | Non-TCD co-supervisor |  | Stakeholder (clinical) |
|  | Collaborator |  | Stakeholder (professional) |
|  | Public/patient/participant collaborator |  | Stakeholder (industrial) |
| **TEAM.C.2 Name** *(Title, Given name, FAMILY NAME)* |  |
| **TEAM.C.3 Email address** |  |
| **TEAM.C.4 Primary/relevant non-TCD affiliation (name of organization)** |  |
| **TEAM.C.5 Job title/role within non-TCD organization** |  |
| **TEAM.C.6 Country/countries** |  |

**PROJ. PROJECT DETAILS**

**PROJ.A 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/Top%20Guidance_Simplified-31st%20Oct.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.*

PROJ.A.1 Title of project

*If your project is a mixed methods study where ethics approval will be sought separately (i.e. different REAMS applications) for the various phases, 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". For guidance on mixed methods studies, see* [*TCD guidance on completion of the application form*](https://www.tcd.ie/research/support/assets/pdf/Top%20Guidance_Simplified-31st%20Oct.pdf)*, p. 26.*

|  |
| --- |
|  |

PROJ.A.2 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.*

|  |  |  |  |
| --- | --- | --- | --- |
| Data collection start date: |  | Data collection end date: |  |
|  |  |  |  |
|  |  | Project end date: |  |

PROJ.A.3 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.*

PROJ.A.4 Project classification

|  |  |  |
| --- | --- | --- |
|  | **YES** | **NO** |
| (a) Is the research WHOLLY an analysis of (i) statutes/legal provisions and/or (ii) legal judgments/cases which have been made public by a judicial process? *(YES potentially facilitates Level 1 self-declaration.)* |  |  |
| (b) Trinity researchers will have access ONLY to aggregate data or data that otherwise fall outside the remit of the General Data Protection Regulation (GDPR). *(YES potentially facilitates Level 1 self-declaration.)* |  |  |
| (c) Could the research have detrimental legal, economic or social consequences for either the participant(s) or their establishment(s)?*(YES indicates Level 3 [Faculty] REC approval is required.)* |  |  |
| (d) Intentions of the project: Does the project – |  |  |
| 1. Involve deception? |  |  |
| 2. Intend to uncover additional illegal activity? |  |  |
| 3. Explore a topic that is potentially intrusive or is 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/Top%20Guidance_Simplified-31st%20Oct.pdf) *for additional requirements.* |  |  |
| 6. Involve none of (d) 1-5 above? |  |  |
| *(If any of (d) 1-5 apply, Level 3 [Faculty] REC approval is required.)* |

PROJ.A.5 State research aim(s) and objective(s), research question or hypothesis (as appropriate).
*(Word limit: 100 words)*

|  |
| --- |
|  |

PROJ.A.6 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)*

|  |
| --- |
|  |

PROJ.A.7 Identify all countries where data are collected or processed

|  |
| --- |
|  |

PROJ.A.8 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.* |  |  |

PROJ.A.9 Is the project funded?

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

**PROJ.B DETAILS OF HUMAN PARTICIPANTS AND THEIR DATA**

**This subsection is required for all projects involving data on humans, UNLESS you have answered YES to PROJ.A.4 (a) or (b).***If not applicable, use the grey highlighter in Word to shade this component.*

**PROJ.B.1 Is your project a mixed methods study?**

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

If YES, please identify the parent study. *(If this is the FIRST study in a mixed methods study, please leave the fields for reference number and title blank.)*

|  |  |
| --- | --- |
| **Parent study REC reference number** | **Parent study project title** |
|  |  |

**PROJ.B.2 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/)*. A PIL template for projects where personal data are not being processed is also available: See Appendix 1 of* [*TCD Guidance on Making an Application*](https://www.tcd.ie/research/support/assets/pdf/Top%20Guidance_Simplified-31st%20Oct.pdf)*.*

**PROJ.B.3 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: HLTH.1.)*

If NO, please provide further information.

|  |
| --- |
|  |

**PROJ.B.4 Will payment be made to research participants?***(Choose one only. 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 |

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

|  |
| --- |
|  |

**PROJ.B.5 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 |

If YES, does the project require a consent declaration form as defined by the HRR?

|  |  |  |  |
| --- | --- | --- | --- |
|  | 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.*

**PROJ.B.6 Could any of the research data DIRECTLY identify any participant?**

*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/Top%20Guidance_Simplified-31st%20Oct.pdf)*.
See PROJ.B.8 below for other project information that has personal data.)*

*If YES, project is not eligible for Level 1; it will be Level 2 (School) or Level 3 (Faculty).*

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

**PROJ.B.7 Could any of the research data INDIRECTLY identify any participant?**

*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/Top%20Guidance_Simplified-31st%20Oct.pdf)*.
See PROJ.B.8 below for other project information that has personal data.)*

*If YES, project is not eligible for Level 1; it will be Level 2 (School) or Level 3 (Faculty).*

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

**PROJ.B.8 Do you process personal data for study administration purposes (*e.g.* contacting individuals)?** *If YES, project is not eligible for Level 1; it will be Level 2 (School) or Level 3 (Faculty).*

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

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 DATA.B.)*

|  |
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**PROJ.B.9 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.)* |
|  | (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/Top%20Guidance_Simplified-31st%20Oct.pdf)*, p. 32.)* |
|  | (d) Children (< 18 years) *(YES indicates Level 3 [Faculty] REC is required.)* |
|  | (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 staff and/or students of Trinity will be participants, see information at* [*https://www.tcd.ie/Communications/internal-communications/email-protocol/*](https://www.tcd.ie/Communications/internal-communications/email-protocol/)*.*

**PROJ.B.10 Only required if project is health research (PROJ.B.5 = 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 |

If OTHER, please describe.

|  |
| --- |
|  |

**PROJ.B.11 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.*

|  |
| --- |
|  |

**PROJ.C Research sites and data sources**

**This subsection is required for all projects involving data on humans, UNLESS you have answered YES to PROJ.A.4 (a) or (b).***If not applicable, use the grey highlighter in Word to shade this component.*

*If there are more than four sites/sources, copy and paste the table below (PROJ.C.1-4) as many times as required.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Site/Source 1** | **Site/Source 2** | **Site/Source 3** | **Site/Source 4** |
| **PROJ.C.1Name of data collection site/ source.** |  |  |  |  |
| **PROJ.C.2Does 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.* |  | No licence/ permission/ approval required |  | No licence/ permission/ approval required |  | No licence/ permission/ approval required |  | No licence/ permission/ approval 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 |
| **PROJ.C.3Name 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.** |  |  |  |  |
| **PROJ.C.4Was 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 |

**PROJ.D OUTLINE OF PROJECT METHODS**

**This subsection is required for all projects involving data on humans, UNLESS you have answered YES to PROJ.A.4 (a) or (b).***If not applicable, use the grey highlighter in Word to shade this component.*

**PROJ.D.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 (PROJ.D.2) you will be asked to name and describe any specific instruments that will be used.*

|  |
| --- |
|  |

**PROJ.D.2 Methods/measurements.** *(Word limit = 100 words for each.)*
*Please add as many additional rows to the table in PROJ.D.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*.*).*

|  |
| --- |
|  |
|  |

**PROJ.D.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 routing to Level 1 (self-declaration), though other parameters may raise risk level.* |
|  | 2. Anonymous surveys *May facilitate routing to Level 1 (self-declaration), though other parameters may raise risk level.* |
|  | 3. Unrecorded and anonymous observation of individuals in public areas *May facilitate routing to Level 1 (self-declaration), though other parameters may raise risk level.* |
|  | 4. Audits of standard practices or tests *May facilitate routing to Level 1 (self-declaration), 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 |

PROJ.D.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.*

If YES,

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

|  |  |
| --- | --- |
|  | 1. Health\* non-trial (\*including psychology, social care) |
|  | 2. Health\* trial (\*including psychology, social care)*Please consult the* [*Health Products Regulatory Authority*](https://www.hpra.ie/homepage/site-tools/search?query=Trials) *for details on registration, ethical and other regulatory requirements for clinical and health trials including medicinal products or medical devices. Note that some medical apps may fall under the medical device regulations.* |
|  | 3. Educational |
|  | 4. Other – please state below |

Classification of OTHER intervention type (if applicable).

|  |
| --- |
|  |

(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.*

|  |
| --- |
|  |

**PROJ.D.5 What is the approximate size of the target population?**

|  |
| --- |
|  |

**PROJ.D.6 What is the proposed sample size, *i.e.* how many participants are to be involved in the study?**

|  |
| --- |
|  |

**PROJ.D.7 What is the justification for this sample size?**

|  |
| --- |
|  |

**PROJ.D.8 Outline the method of analysis.** *(Word limit = 100 words.)*

|  |
| --- |
|  |

**SMPL. 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 PROJ.B.2.)***If not applicable, use the grey highlighter in Word to shade this component.*

**SMPL.1 Outline the sampling method.**

|  |
| --- |
|  |

**SMPL.2 Describe the time commitment of a participant.**

|  |
| --- |
|  |

SMPL.3 Will the research require/use a gatekeeper?

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

If YES, complete (a)-(c) below.

|  |
| --- |
| **(a) Outline the position/role of the gatekeeper within the organisation.** |
| **(b) Detail the role of the gatekeeper in the project.** |
| **(c) Is there a dependent relationship between the gatekeeper and the participants?**

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

If YES, outline how this is going to be managed to mitigate against the dependencies.

|  |
| --- |
|  |

 |

**SMPL.4 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).*

|  |
| --- |
|  |

**HLTH. HEALTH RESEARCH**

**The HEALTH RESEARCH section must be completed if the project is health research as defined by the Health Research Regulations (PROJ.B.5).***If not applicable, use the grey highlighter in Word to shade this component.*

*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.*

**HLTH.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.* |

**HLTH.2 Only required if an intervention is part of the project protocol (PROJ.D.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 |

**HLTH.3 Will the project involve the administration of any substance(s) or require participants to refrain from taking any substance(s)?**

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

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

|  |
| --- |
|  |

**HLTH.4 Will there be ongoing clinical supervision of the participants by a duly insured clinical practitioner during the project?**

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

**HLTH.5 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 |

**HLTH.6 Will permission be sought from the research participants to disclose information (for example, information about adverse outcomes) to their GPs?**

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

**CONS. CONSENT**

**The CONSENT section must be completed if you will obtain consent/assent from participants (PROJ.B.3).***If not applicable, use the grey highlighter in Word to shade this component.*

**CONS.1 How will consent be obtained, and by whom?**

|  |
| --- |
|  |

CONS.2 Do your participants require support to give consent?

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

If YES, provide further information.

|  |
| --- |
|  |

CONS.3 Do you require assent from participants, (*e.g*. because of their vulnerability)?

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

If YES, complete (a)-(c) below.

|  |
| --- |
| **(a) Provide further information on the need for assent.** |
| **(b) How will assent be obtained and by whom?** |
| **(c) Provide any further information relevant to the assent process.** |

CONS.4 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.*

CONS.5 What is the time interval between giving information and securing consent?

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

If LESS THAN 7 DAYS, provide further information.

|  |
| --- |
|  |

**CONS.6 Describe how you will inform participants about the use of their personal data.**

|  |
| --- |
|  |

**CONS.7 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.*

|  |
| --- |
|  |

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

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

**RISK.A RISK OR HARM TO RESEARCHER**

**RISK.A.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 |  | 5. Hospital/clinic |  | 9. Other – please state below |
|  | 2. Participants' place of work |  | 6. Laboratory |  | *Description of OTHER setting type (if applicable):* |
|  | 3. Participants' home |  | 7. In a foreign country |  |
|  | 4. Classroom |  | 8. Online |  | 10. None |

RISK.A.2 Describe the potential risk(s), if any, to the researcher(s) and your plan for mitigation.
*Choose from the following list of potential risks. If you select OTHER, please briefly outline the nature of the ‘other’ risk.*

|  |  |
| --- | --- |
| *1. The topic explored is potentially intrusive/harmful or may potentially endanger the researcher* | *4. Other (please provide details in table)* |
| *2. Emotional risks including stress, distress or discomfort* | *5. None* |
| *3. Physical risks including bodily harm, aggression or violence* |  |

*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 column and leave the remaining columns blank. Add as many rows to the table as required – one for each individual risk.*

|  |  |  |  |
| --- | --- | --- | --- |
| (a) Identify the risk(s) | (b) Estimate the impactLow/Medium/High*(Worst case scenario)* | (c) Estimate the probability/likelihoodLow/Medium/High | (d) Detail the mitigation measure(s) |
|  |  |  |  |
|  |  |  |  |

RISK.A.3 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* [*https://www.tcd.ie/research/support/assets/pdf/Top%20Guidance\_Simplified-31st%20Oct.pdf*](https://www.tcd.ie/research/support/assets/pdf/Top%20Guidance_Simplified-31st%20Oct.pdf)*.*

**RISK.B RISK OR HARM TO SITE, ENVIRONMENT OR SOCIETY**

RISK.B.1 Describe the potential risk(s), if any, to the data collection site (including confidentiality of site), environment or society, and your plan for mitigation.
*Choose from the following list of potential risks. In each case, provide brief details of the nature of the risk. (E.g. “Risk to data collection site: Reputational risk if accidental disclosure of site’s identity.”)*

|  |  |  |  |
| --- | --- | --- | --- |
| *1. Risk to data collection site* | *2. Risk to environment* | *3. Risk to society* | *4. None* |

*Please include all potential risks, even if the chance of occurrence is low. If no risks to the site, environment or society have been identified, indicate 'None' in the first column and leave the remaining columns blank. Add as many rows to the table as required – one for each individual risk.*

|  |  |  |  |
| --- | --- | --- | --- |
| (a) Identify the risk(s) | (b) Estimate the impactLow/Medium/High*(Worst case scenario)* | (c) Estimate the probability/likelihoodLow/Medium/High | (d) Detail the mitigation measure(s) |
|  |  |  |  |
|  |  |  |  |

**RISK.C RISK OR HARM TO PARTICIPANTS**

RISK.C.1 Does any member of the research team have a dependent relationship with the participants?

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

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.

|  |
| --- |
|  |

RISK.C.2 Describe the potential risk(s), if any, to the participants and your plan for mitigation.

*Choose from the following list of potential risks. If you select OTHER, please briefly outline the nature of the ‘other’ risk.*

|  |  |  |
| --- | --- | --- |
| *1. Inconvenience* | *5. Financial risks, including exposure or loss* | *9. Other (please provide details in table)* |
| *2. Physical risks* | *6. Loss of privacy* | *10. None* |
| *3. Emotional risks, including stress, distress or discomfort* | *7. The topic explored is potentially intrusive* |  |
| *4. Reputational risks* | *8. The research may be harmful or may potentially endanger participants* |

*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 column and leave the remaining columns blank. Add as many rows to the table as required – one for each individual risk.*

*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.*

|  |  |  |  |
| --- | --- | --- | --- |
| (a) Identify the risk(s) | (b) Estimate the impactLow/Medium/High*(Worst case scenario)* | (c) Estimate the probability/likelihoodLow/Medium/High | (d) Detail the mitigation measure(s) |
|  |  |  |  |
|  |  |  |  |

**RISK.D PARTICIPANT BENEFITS AND CONFIDENTIALITY**

RISK.D.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 |

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

|  |
| --- |
|  |

**RISK.D.2 Outline any direct benefits to research participants of participation.**

|  |
| --- |
|  |

**RISK.E CONFLICT OF INTEREST (arising from personnel)**

RISK.E.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 FUND.B in Funding section.)*

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

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

|  |
| --- |
|  |

**FUND. FUNDING**

**The FUNDING section (all subsections) must be completed for all projects that are funded (PROJ.A.9).***If not applicable, use the grey highlighter in Word to shade this component.*

**FUND.A FUNDING DETAILS**

**FUND.A.1 Insert TCD Research Proposal and Awards Management System (RPAMS) number if applicable and available.**

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

**FUND.A.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*** |
|  |  |
|  |  |

**FUND.A.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.**

|  |
| --- |
|  |

**FUND.A.4 Will the results of the project be used or disclosed for commercial purposes?**

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

**FUND.A.5 Please clarify which party/parties shall have the commercialisation and/or intellectual property rights.**

|  |
| --- |
|  |

**FUND.B CONFLICT OF INTEREST (arising from funding or commercialisation)**

**FUND.B.1 Are you aware of any possible conflict of interest arising from the funding or commercialisation of this project?**

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

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

|  |
| --- |
|  |

**FUND.B.2 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 |

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

|  |
| --- |
|  |

**BIOL. HUMAN BIOLOGICAL SAMPLES**

**The HUMAN BIOLOGICAL SAMPLES section must be completed if the project involves any of the following (PROJ.A.8):**

* **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 (PROJ.D) and any relevant appendices, including your materials for participants.*

**BIOL.1 Will the samples in any form be stored for any period?**

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

If YES:

**(a) State what type of samples will be stored.**

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

**(d) Will the samples in any form be stored for any period after the project's completion?**

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

**BIOL.2 Does the project involve the use of genetic data?**

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

**DATA DATA PROTECTION**

**DATA.A 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.*

**DATA.A.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 |

**DATA.A.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 |

**DATA.B DATA PROTECTION ASSESSMENT**

**The DATA PROTECTION ASSESSMENT 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.*

**DATA.B.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 |

**DATA.B.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)*.*

|  |  |  |  |
| --- | --- | --- | --- |
|  | < 30 |  | > 30 |

**DATA.B.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)*.*

|  |
| --- |
|  |

**DATA.B.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)*.*

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

**DATA.B.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 |

If YES, name the unit(s) with which data are shared.
*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)*.*

|  |
| --- |
|  |

**DATA.B.6 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:

(a) 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*** |
|  |  |  |
|  |  |  |

(b) Describe what IT due diligence you 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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**DATA.B.7 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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**DATA.B.8 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.*

**DATA.B.9 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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**DATA.C DATA PROTECTION RISK ASSESSMENT (DPRA)**

**The DATA PROTECTION ASSESSMENT 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.*

*The questions in this section will assess the risk to the personal data processed for your research project and determine whether a further, more detailed assessment - a Data Protection Impact Assessment (‘DPIA’) - is required.*

**DATA.C.1 Complete the table below.***If you answer YES to two or more of the questions then your research project will additionally require completion of the DPIA section of this application form (DATA.D).*

|  | **YES** | **NO** |
| --- | --- | --- |
| 1. Does the project involve matching or combining data sets?*See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.3.1.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.3.1.pdf)*.* |  |  |
| 2. Are the topics explored in the project intrusive or sensitive in nature?*See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.3.2.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.3.2.pdf)*.* |  |  |
| 3. Does the project use personal data on a large scale? *(NB: Large scale does not equate to large number.) See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.3.3.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.3.3.pdf)*.* |  |  |
| 4. Does the project involve the processing of personal data relating to participants who belong to a vulnerable segment of the population?*See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.3.4.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.3.4.pdf)*.* |  |  |
| 5. Are the participants individuals with a rare condition or disease?*See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.3.5.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.3.5.pdf)*.* |  |  |
| 6. Does the project involve the use of new technologies or organisational solutions?*See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.3.6.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.3.6.pdf)*.* |  |  |
| 7. Does the project involve processing of special category data or data relating to criminal convictions and/or offences (sensitive personal data)?*This includes (but is not limited to) health, genetic and ethnicity 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/2.11.3.7.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.3.7.pdf)*.* |  |  |
| 8. Does the project involve systematic monitoring, tracking or observation of individuals' location or behaviour?*See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.3.8.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.3.8.pdf)*.* |  |  |
| 9. 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?*See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.3.9.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.3.9.pdf)*.* |  |  |
| 10. Does the project involve the evaluation or scoring, including profiling and predicting, of participants to make generalisations about an individual that could lead to significant decisions being made that could directly affect the individual?*See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.3.10.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.3.10.pdf)*.* |  |  |
| 11. Could the project prevent individuals from exercising a right, using a service, or fulfilling a contract?*See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.3.11.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.3.11.pdf)*.* |  |  |

**DATA.D DATA PROTECTION IMPACT ASSESSMENT (DPIA)**

**The DATA PROTECTION IMPACT ASSESSMENT section must be completed if you answered YES to two or more of the questions in the Data Protection Risk Assessment (DATA.C.1) above.***If not applicable, use the grey highlighter in Word to shade this component.*

*Please review the questions and associated guidance in the subsection below carefully.*

**DATA.D.1 Why is the processing of personal data (*i.e*. data relating to an identified or identifiable living individual) necessary for the project?***See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.1.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.1.pdf)*.*

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**DATA.D.2 How often (at what frequency) will you be collecting data from individual participants?***See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.2.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.2.pdf)*.*

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**DATA.D.3 Please indicate which Article 6 lawful basis/bases you are relying on for the use of personal data.** *Choose all that apply. A legal basis is required to process personal data: Please review guidance carefully before answering:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.3.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.3.pdf)*.*

|  |  |
| --- | --- |
|  | 1. Consent |
|  | 2. Performance of contract |
|  | 3. Legal obligation |
|  | 4. Public interest or exercise of official authority |
|  | 5. Vital interest of data subjects |
|  | 6. Legitimate interest |

**DATA.D.4 Please indicate which Article 9 condition(s) you are relying on for the use of special category personal data.** *Choose all that apply.
See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.5.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.5.pdf)*.*

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| --- | --- |
|  | 1. Archiving purposes in the public interest/scientific or historical research purposes/statistical purposes |
|  | 2. Explicit consent |
|  | 3. Employment/DSP\* rights *\*Department of Social Protection* |
|  | 4. Not-for-profit body with a political, philosophical, religious or trade union aim |
|  | 5. Vital interests of the data subject or another person carried out internally by a not-for-profit organisation |
|  | 6. Necessary for the establishment, exercise or defence of legal claims |
|  | 7. Information that has already been made public by the data subject |
|  | 8. Preventive or occupational medicine |
|  | 9. Necessary for a substantial public interest |
|  | 10. Necessary for reasons of public interest in the area of public health |
|  | N/A. No special category personal data are used in this project. |

**DATA.D.5 Describe plans that are in place for responding to any requests from individuals in relation to their data protection rights.***See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.6.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.6.pdf)*.*

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**DATA.D.6 How will the data be kept accurate and up to date and of sufficient quality for the research project?***See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.7.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.7.pdf)*.*

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**DATA.D.7 Purpose limitation: Is the processing for the intended purpose only, or is there a possibility that additional purposes may be added at a later date?***See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.8.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.8.pdf)*.*

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**DATA.D.8 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.***See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.9.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.9.pdf)*.*

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**DATA.D.9 Who is authorised to access the data? Describe how this access is controlled.***See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.10.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.10.pdf)*.*

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**DATA.D.10 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 and mixture of uppercase, lowercase and special characters.***It is a requirement that the answer to this question is YES.
See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.11.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.11.pdf)*.*

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

**DATA.D.11 Are you using multi-factor authentication (two step sign in) to access all systems which store research data?**

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

**DATA.D.12 (a) Detail how and when you will code/pseudonymise personal data you are using for the project (if applicable).** *Mark N/A if you will not be coding/pseudonymising personal data.*

*See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.12.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.12.pdf)*.*

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**(b) Detail how and when the personal data will be archived/anonymised/deleted/destroyed (as applicable).**

*See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.12.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.4.12.pdf)

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**DATA.E PROCESSING RISK**

**The PROCESSING RISK 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.*

**DATA.E.1 List the processing risks of any kind. For each, estimate its severity/impact (low, medium or high) and its likelihood (low, medium or high), and outline your proposed solution(s)/mitigation action(s).** *Add as many rows as required.
See guidance:* [*https://www.tcd.ie/dataprotection/assets/pdf/2.11.5.pdf*](https://www.tcd.ie/dataprotection/assets/pdf/2.11.5.pdf)*.*

|  |  |  |  |
| --- | --- | --- | --- |
| Processing risk | **Severity/impact** Low/med/high | **Likelihood**Low/med/high | **Solution/mitigation** |
|  |  |  |  |
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**DATA.F CLOSING SECTION**

**This CLOSING SECTION is optional.***If not applicable, use the grey highlighter in Word to shade this component.*

**DATA.F.1 Include any additional information in respect of the study that may be relevant.**

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**DECL. DECLARATIONS**

**DECL.1 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** |  |

**DECL.2 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** |  |

**DECL.3 Supervisor's declaration**

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

* I have read this application and all related documents.
* I am satisfied that these are in line with the School's ethical criteria and all relevant Trinity policies and regulations (*e.g.* data protection, data retention, IP *etc*.)

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

**APP. APPENDICES**

The appendices 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 appended, as well as any others that you consider relevant to your application.

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

**All appendices must be numbered, and must be combined with this application form for submission as a single Word/pdf file. 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 certificationAll 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** |  |
| DPIA(s) for external site(s), if required by external site(s) *Note that TCD’s DPIA and DPRA are in the body of this application form and do not require separate appendices.* |  |
| 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)** |  |
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