|  |  |
| --- | --- |
|  | **Dublin City University**  **RESEARCH ETHICS COMMITTEE**  **APPLICATION FORM FOR ETHICAL REVIEW OF A RESEARCH PROJECT INVOLVING HUMAN PARTICIPANTS** |

Any queries relating to this form should be e-mailed to the DCU Research Ethics Committee (REC) at [rec@dcu.ie](mailto:rec@dcu.ie) The REC Review Process is outlined in the Information and Guidance section of the [DCU Research Ethics webpage](https://www.dcu.ie/researchsupport/research-ethics)

Please note that the REC is not responsible for overseeing insurance requirements. Applicants should refer to the [DCU Insurance webpage](https://www.dcu.ie/finance/travel-insurance-policy-0%20) for guidance. It is incumbent upon every applicant to ensure that the appropriate insurance cover is in place for their project.

If your research involves collecting or processing [personal data](https://www.dcu.ie/ocoo/data-protection-key-points-dcu-researchers), you must first complete the DCU online Data Protection training course and review the [“Data Protection – Key Points for DCU Researchers”](https://www.dcu.ie/ocoo/data-protection-key-points-dcu-researchers) guidance from the Data Protection Unit to assist you in meeting your legal obligations under GDPR and associated Irish law.

If your research requires approval from the [Biological Safety Committee (BSC)](https://www.dcu.ie/scienceandhealth/faculty-health-and-safety) this must be in place prior to REC submission. Contact [bio.safety@dcu.ie](mailto:bio.safety@dcu.ie).

**Please provide a response for each section of the form.**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**SECTION 1 – GENERAL DETAILS**

**1.1 Project Title**

|  |
| --- |
|  |

**1.2 Applicant Details**

DCU Principal Investigator(s):*In the case of all doctoral and Research Masters projects, the supervisor must be listed as Principal Investigator.*

|  |  |  |
| --- | --- | --- |
| Name | School/Unit | E-mail |
|  |  |  |
|  |  |  |
|  |  |  |

Other Investigators: *Including any external to DCU.*

|  |  |  |
| --- | --- | --- |
| Name | School/Unit/External Institution | E-mail |
|  |  |  |
|  |  |  |
|  |  |  |

**1.3 Key Project Dates**

|  |  |  |
| --- | --- | --- |
| Proposed start date for data collection | Proposed end date for data collection | Proposed project completion date |
|  |  |  |

**1.4 Please tick the checkbox for the appropriate level of required review:**

*Consult the Level of Review advice in the Information and Guidance section of the* [*DCU Research Ethics webpage*](https://www.dcu.ie/researchsupport/research-ethics)*).*

|  |  |  |
| --- | --- | --- |
| Full Committee | Expedited | Notification |

**1.5 Please indicate if this project is for an academic award** (tick N/A checkbox if not)

|  |  |  |  |
| --- | --- | --- | --- |
| PhD | Other Doctoral Programme | Research Masters | N/A |

**1.6 Please confirm the location(s) where the research will be carried out.**

*If research will be carried out abroad, you will need to address the ethical challenges raised by this in Section 3 of your application - consult the Conducting Research Abroad document in the Ethics Resources and Guidelines section of the* [*DCU Research Ethics webpage*](https://www.dcu.ie/researchsupport/research-ethics)*).*

|  |
| --- |
|  |

**1.7 Please state what additional permissions may be required to access participants.**

*Specify from whom the permission is required (e.g. a school Board of Management), and when their written approval will be obtained.*

|  |
| --- |
|  |

**1.8 Has this project has been submitted to another research ethics committee for review?**

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

*If yes, please provide details and attach relevant documentation.*

|  |
| --- |
|  |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**SECTION 2 – PROJECT DESIGN AND METHODOLOGY**

**Research Overview - Please respect the indicated word counts in the following sections and explain all acronyms in full text the first time they appear.**

**2.1 Provide a brief description of the research (max 250 words):**

*Please use lay language, include the scientific/theoretical background of study and a justification as to why this research project should proceed.*

|  |
| --- |
|  |

**2.2 Please state the aims and objectives of the research project (max 200 words)**

|  |
| --- |
|  |

**2.3 Please state the hypothesis and/or research question (in bullet points – max 100 words)**

|  |
| --- |
|  |

**2.4 Please state your overall methodology (max 400 words):**

*Include the tasks participants will be asked to do, estimated time commitment and the methods of analysis to be used.*

|  |
| --- |
|  |

**2.5 Please confirm your methods of data collection:**

*Tick all relevant check boxes and provide details for each one, including any devices used to collect data.*

|  |  |
| --- | --- |
| Method | Describe briefly |
| Interviews or focus groups |  |
| Surveys/questionnaires |  |
| Audio/video recordings |  |
| Public observations |  |
| Persons in public office |  |
| Using existing data (incl. secondary data) |  |
| Using human derived material (biological samples) |  |
| Standard tests (educational/personality etc.) |  |
| Standard educational practices |  |
| Other (please specify) |  |

**2.5.1 Use of Artificial Intelligence in Research**

*Does the research make significant use of Artificial Intelligence such that ethical issues are raised? (See the DCU Guidance on the ethical use of Artificial Intelligence (AI) in Research available on the* [*Research Ethics webpage*](https://www.dcu.ie/researchsupport/research-ethics)*)*

*Please tick as appropriate*

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

*If ‘Yes’, please confirm below that you have completed the Guiding Questions for Self-Assessment on the Ethical Use of AI in Research available on the Research Ethics webpage. Please attach completed Self-Assessment to this application form.*

|  |  |
| --- | --- |
| Self-Assessment Attached | N/A |
|  |  |

**2.6 Please list the Investigator qualifications, experience and skills relevant to conducting the research for this project** (max 200 words).

*Please complete for all investigators and specify who will be carrying out which elements of the research project.*

|  |
| --- |
|  |

**2.7 Please confirm who the participants on this study will be, including group size and composition:**

*Include associated demographic characteristics, and state how your proposed sample size was determined (e.g. power analysis)*

|  |
| --- |
|  |

**2.8 Please outline your recruitment process, including where you are sourcing participants from and your criteria for inclusion/exclusion:**

*Where gatekeepers are involved, describe their role.*

|  |
| --- |
|  |

**2.9 Addressing participant vulnerability. Please identify if your participants fall into any of the following categories by ticking the relevant box/boxes below. Describe the special arrangements being made to protect them.**

*If your participants are not in any of these categories, tick N/A*

|  |
| --- |
| N/A |
| Children under 18 years of age |
| Persons in unequal relationships with the researcher *(e.g. lecturer-student, therapist-client, employer-employee)* |
| People with a recognised or diagnosed intellectual, physical or mental impairment |
| People confined to institutions *(e.g. prisoners, residents in 24 hr nursing facilities)* |
| People who have undergone traumatic or adverse emotional events |
| People with diminished cognitive ability |
| Marginalised sections of society |
| Other (please specify) |
| ***Special arrangements:*** |

**2.10 Involvement of children under 18 years of age – if your participants are in this category, please confirm compliance with the following:**

*If your participants are not in this category, tick N/A*

|  |
| --- |
| N/A |
| We confirm that we have read and agree to act in accordance with the DCU Child Protection policy and procedures (*as per the* [*DCU Child Protection Unit webpage*](https://www.dcu.ie/ocoo/child-protection-unit)*)* |
| We confirm that we have put in place safeguards for the children participating in the research |
| We confirm that we have supports in place for children who may disclose current or historical abuse (whether or not this is the focus of the research) |
| We confirm that all requirements will be met prior to commencing the research *(e.g. TUSLA Children First Training completed, Garda Vetting in place)* |

**2.11 Please confirm how the results of the research will be disseminated:**

*In line with encouraging institutional Open Research practices, please note that the use of open access publishing is recommended. Further information on this is available via* [*https://www.dcu.ie/library/open-research-open-access*](https://www.dcu.ie/library/open-research-open-access).

*Please include a statement on whether the participants will be provided with any information as to the findings or outcomes of the project.*

|  |
| --- |
|  |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**SECTION 3 – ETHICAL ISSUES AND RISK MANAGEMENT**

**3.1 Please identify all ethical issues which may arise in the course of this research. Describe how these may incur potential risks to participants and the steps being taken to address or minimise them?**

*Potential risks can be physical, psychological, social, legal, etc. Please include details of any additional support being provided for participants during/after the study.*

|  |
| --- |
|  |

**3.2 Please identify the potential benefits (direct and/or indirect) to those participating in this research:**

*Potential benefits should outweigh the potential risks to participants – this section should never be blank.*

|  |
| --- |
|  |

**3.3 Please describe what measures/protocols you have put in place in the event of any unexpected outcomes or adverse effects to participants arising from involvement in the research:**

|  |
| --- |
|  |

**3.4 Do you intend to provide payment or incentives to participants?**

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

*If Yes, please consult the REC Guidelines on the Use of Compensation and Incentives (in the Ethics Resources and Guidelines section of the* [*DCU Research Ethics webpage*](https://www.dcu.ie/researchsupport/research-ethics)*) before providing additional details below.*

|  |
| --- |
|  |

**3.5 Does this research raise any potential risks for the researchers themselves?**

*Please consider the location/environment where the research is being conducted, exposure to distressing data content etc.*

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

*If Yes, please describe further and explain what risk management procedures will be put in place to minimise these risks to researchers:*

|  |
| --- |
|  |

**3.6 Please confirm how the research is being funded:**

|  |  |
| --- | --- |
| Self-funded | Externally funded |

*Include details of any external funding of the research, whether in part or in full. If the research is externally funded, please include this information in the Participant Information Sheet/s.*

|  |
| --- |
|  |

**3.7 Does this research raise any potential conflict of interest?**

*Please consider any potential real or perceived conflicts of interest that might influence the integrity of the research, or give rise to bias in conducting and reporting the research, or affecting publication (consult the* [*DCU Conflict of Interest Policy*](https://www.dcu.ie/policies/conflict-interests-policy-staff-only) *for assistance).*

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

*If Yes, please identify and explain the steps being taken to address that conflict:*

|  |
| --- |
|  |

**3.8 Please describe how the conduct of the research will be monitored:**

*Regular oversight by the PI is required to ensure the project conforms to the procedures set out in this application (especially where several people are involved in carrying out the research procedures).*

|  |
| --- |
|  |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**SECTION 4 – CONFIDENTIALITY AND DATA MANAGEMENT**

**4.1 Considering your previous response in section 2.5 of the form, please confirm whether you are collecting or processing personal data in this research project:**

*Personal data is any information about a living person, where that person is either identified, or could be identified from the data itself, or when it is combined with other data.* *This includes paper based, electronic and biological samples data. If your data is fully and completely anonymous, it is not personal data.*

***N.B. Researchers are advised to anonymise potentially identifiable data as soon as possible in the research process****. Where relevant, researchers are advised to ensure participants are advised not to include any personally identifying information in any free-text space/s in anonymous questionnaires/surveys.*

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

*If Yes, please confirm your compliance with the following by ticking the checkboxes:*

|  |
| --- |
| We confirm that we have completed the DCU Data Protection training module on Loop. |
| We confirm that we have read the [“Data Protection – Key Points for DCU Researchers”](https://www.dcu.ie/ocoo/data-protection-key-points-dcu-researchers) guidance on the DCU Data Protection Unit (DPU) website and agree to protect and manage our data in accordance with same. |
| We have assessed the degree of risk inherent in the personal data being used in the research project, and confirm that all DPU GDPR requirements have been met prior to submitting this application *(e.g. completion of Data Protection questionnaire, confirmation that any survey tool being used is GDPR compliant, that required Data Processing or Sharing Agreements will be in place, etc.)* |

**4.2 Access to data – please confirm whether access to participant data isconfined to the investigators named on this application:**

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

*If No, please name who the other individuals are and why they need access. Any proposed transfer of data (including outside of the EU) should be detailed here.*

|  |
| --- |
|  |

**4.3 Data storage – please confirm compliance with the following:**

|  |
| --- |
| Data collected on mobile devices will be protected with a strong password/passphrase at a minimum, and/or encrypted if the device supports it |
| Data will be removed from mobile devices as soon as is practicable and stored in a secured location in DCU (on server or institutional Google Drive) |
| Paper based data will be held securely in locked cabinets in DCU, with access restricted to the named researchers |
| *Specific arrangements in relation to biological samples should be stated here:* |
| *Any exemptions to the above compliance statements should be justified here:* |

**4.4 Please confirm who will be responsible for the secure storage of data generated by the research:**

*Name the relevant DCU investigator/s.*

|  |
| --- |
|  |

**4.5 Please confirm how long the data will be held for:**

*For personal data, consult section 15: Retention of Personal Data in the* [*“Data Protection – Key Points for DCU Researchers”*](https://www.dcu.ie/ocoo/data-protection-key-points-dcu-researchers) *guidance on the DCU Data Protection Unit (DPU) website.*

|  |
| --- |
|  |

**4.6 Please confirm the procedure for managing study data at the completion of the research project:**

*Please tick the relevant checkbox and complete the associated follow-up section for that category.*

|  |  |  |
| --- | --- | --- |
| Archived | Destroyed | Other |

**4.6.1 Archived data (data that will be retained beyond the completion of the project)**

*In line with encouraging institutional Open Research practices, please note that the use of trusted data repositories or archives is recommended. Further information is available via* [*https://www.dcu.ie/library/open-research-fair-data*](https://www.dcu.ie/library/open-research-fair-data)

*Please provide the following details:*

|  |  |
| --- | --- |
| Name the DCU staff member responsible for archival and future use of data |  |
| Confirm whether the data will be made available to other researchers, and if so, how? |  |
| Confirm how the data will be prepared for archive (e.g. will datasets be anonymised) |  |
| Confirm where the data will be archived and who will be allowed to access it |  |

**4.6.2 Destroyed data (data that will be destroyed once the research has been completed)**

*Please provide the following details – Note: for student projects, the supervisor must take responsibility for data destruction if there is no guarantee the student will have access to the data at the time of destruction.*

|  |  |
| --- | --- |
| Please justify why the data will be destroyed |  |
| Name the DCU researcher responsible for destruction of data |  |
| Confirm when the data will be destroyed (specify date) |  |
| Confirm compliance with the following destruction methods (tick relevant boxes) | Electronic data will be overwritten/securely deleted  Paper based data will be confidentially shredded  Medical samples will be disposed in accordance with the relevant DCU approved SOP |

**4.6.3 Other - Please explain what will happen to the data if not being archived or destroyed:**

|  |
| --- |
|  |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**SECTION 5 – PARTICIPANT INFORMATION AND INFORMED CONSENT PROCEDURES**

**5.1 Please confirm that the following items have been addressed in your Participant Information Sheet:**

*The items should be used as headings in the information sheet. Note the language used**under each item must reflect the participant age group and corresponding comprehension level– if your participants have different comprehension levels (e.g. both adult and child participants) then separate sheets must be prepared for each set. Templates are available via the* [*REC Forms - Applications, Templates and Amendments*](https://www.dcu.ie/researchsupport/research-ethics) *section of the Research Ethics website****.***

|  |  |  |
| --- | --- | --- |
| **Checklist – tick the relevant check box for each item** | **Yes** | **No** |
| Introductory Statement (Researcher names and titles, school, title of the research study) |  |  |
| What is this research about? |  |  |
| Why is this research being conducted? |  |  |
| Why have you been invited to take part? |  |  |
| What will happen if you decide to take part in this research study? |  |  |
| How will your data be used? |  |  |
| How will your privacy be protected (including any legal limits to confidentiality)? |  |  |
| What are the benefits of taking part in this research study? |  |  |
| What are the risks of taking part in this research study? |  |  |
| Can you change your mind at any stage and withdraw from this study? |  |  |
| How will you find out what happens with this project? |  |  |
| Contact details for further information |  |  |

*If you marked any item as No, please explain and justify why:*

|  |
| --- |
|  |

**5.2 Informed Consent Procedures – please confirm whether written consent is to be obtained:**

*Please tick the relevant checkbox*

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

*If Yes, describe the procedures by which written consent will be obtained. If you are involving child participants, you will also need to obtain their written assent. Templates are available via the* [*REC Forms - Applications, Templates and Amendments*](https://www.dcu.ie/researchsupport/research-ethics) *section of the Research Ethics website****.***

|  |
| --- |
|  |

*If No, describe the procedures regarding how consent/assent will be obtained:*

|  |
| --- |
|  |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**SECTION 6 – SUBMISSION CHECKLIST AND RESEARCHER DECLARATION**

**6.1 Please confirm all required supplementary documentation to be included in this application within Section 7:**

|  |  |  |
| --- | --- | --- |
| **Checklist – tick the relevant check box for each item** | **Yes** | **N/A** |
| Participant Information Sheet/s (Template used) |  |  |
| Informed Consent Form/s (Template used) |  |  |
| Informed Assent Form/s (Template used) |  |  |
| Recruitment Advertisement |  |  |
| Questionnaire/Survey |  |  |
| Interview/Focus Group Questions |  |  |
| Debriefing Material |  |  |
| References |  |  |
| Self-Assessment Form on use of AI in research |  |  |
| Approval from another Research Ethics Committee |  |  |
| Evidence of other external approvals (e.g. Board of Management letter) |  |  |
| Evidence of internal approvals (e.g. BSC approval review letter) |  |  |
| Other – provide details here: |  |  |

**6.2 Signed Declaration**

*By submitting this form, the applicant (and supervisor if applicable) agree/s to the following:*

*The information contained herein is, to the best of my knowledge and belief, accurate. I have read the University’s current research ethics guidelines, and accept responsibility for the conduct of the procedures set out in the attached application in accordance with the form guidelines, the* [*REC guidance and resources*](https://www.dcu.ie/researchsupport/research-ethics)*,* *the University’s* [*Conflict of Interest Policy*](https://www.dcu.ie/policies/conflict-interests-policy-staff-only)*, its* [*Code of Good Research Practice*](https://www.dcu.ie/policies/code-good-research-practice) *and any other condition laid down by the Dublin City University Research Ethics Committee. I have attempted to identify all risks related to the research that may arise in conducting this research and acknowledge my obligations and the rights of the participants.*

*I also acknowledge my requirement to be informed as to other duties and legal obligations applying to my research, and to comply with these duties and obligations – this includes being informed about DCU Data Protection guidelines for researchers, DCU Child Protection policy and procedures (where relevant) and DCU Insurance requirements.*

*I and my co-investigators and/or supporting staff have the appropriate qualifications, experience and facilities to conduct the research set out in the attached application and to deal with any emergencies and contingencies related to the research that may arise. Research will not commence until required consents and approvals are in place.*

**Electronic Signature(s): Please include the names and signatures of all those who will contribute significantly to the research project.**

*For student projects the supervisor must be listed as Principal Investigator, and sign here. The student can be named and sign underneath.*

*Principal Investigator(s)/Main Supervisor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Print Name(s) here: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

**Electronic signature of student researcher (if applicable)**

*Student researcher’s signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Print Name here: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**SECTION 7 – SUPPLEMENTARY DOCUMENTATION**

**Please attach all required documentation as confirmed by you in the previous section. The application should then be saved as one file in PDF format before submission via the** [**Research Ethics Application Portal**](https://loop.dcu.ie/course/view.php?id=45490)**on Loop**