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|  | **Dublin City University****RESEARCH ETHICS COMMITTEE**APPLICATION FOR APPROVAL OF A PROJECT INVOLVING **HUMAN PARTICIPANTS****Application No.** *(office use only)*DCUREC/2021/**\_\_\_\_**  |

**Please read the following information carefully before completing your application. Failure to adhere to these guidelines will make your submission ineligible for review.**

* **Applications must be submitted via the Research Ethics Application Portal** [**here**](https://loop.dcu.ie/course/view.php?id=45490)– no hardcopy required**. All queries relating to submission should be e-mailed to the DCU Research Ethics Committee (REC) at** **rec@dcu.ie**
* **Section 4 of this form addresses the possible data protection issues of the proposed research and it must be completed prior to making a formal REC application.**
* **Student applicants must include their supervisor as an investigator on the Research Ethics Application Portal** – this applies to all masters by research and PhD students. The form should be checked, approved and signed by the supervisor in advance of submission to REC. ***NB – Taught Masters and Undergraduate students apply for ethical review via their local ethics review panel, not via REC.***
* **The application should consist of one electronic file only,** with an electronic signature from the PI (and supervisor if applicable). The completed application must incorporate all supplementary documentation, especially those being given to the proposed participants. The application will go through an initial triage process and will be returned to the applicant(s) if the form is incomplete or documentation is missing. If extensive changes are required, it will be reviewed at the next REC committee meeting. The application must be proofread and spellchecked before submission to the REC**.**
* **All sections of the application form must be answered as instructed and within the word limits given.**

Applications which do not adhere to all of these requirements will not be accepted for review and will be returned directly to the applicant.

Applications must be completed on the form; answers in the form of attachments will not be accepted, except where indicated. No hardcopy applications will be accepted. **Research must not commence until written approval has been received from the Research Ethics Committee.**

**Note: 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****.** Please attach the responses from these committees to this submission as directed below.

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| **PROJECT TITLE** |  |
| **PRINCIPAL INVESTIGATOR(S)***The named Principal Investigator is the person with primary responsibility for the research project. In the case of PhD/D.Ed./MSc Research projects the supervisor* ***must*** *be listed as Principal Investigator, in addition to the student.*  |  |
| **START AND END DATE** |  |
| **LEVEL OF RISK***Please indicate whether this project requires (a) notification (b) expedited* ***or*** *(c) full committee review. Justification for your choice is required under section 3.1* |  |

**1. ADMINISTRATIVE DETAILS**

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| **PROJECT TYPE:****(mark Y to as many as apply)** | Research Project | … | Funded Consultancy | … |
| Clinical Trial | … |
|  | Student Research Project (please indicate level below, e.g. PhD/D.Ed./MSc Research) | … | Other - Please Describe:  | … |
|  |  PhD / Other Doctorate | … |
|  |  D.Ed. |  |
|  |  MSc Research | … |

**1.1 INVESTIGATOR CONTACT DETAILS**

**PRINCIPAL INVESTIGATOR(S):** In the case of PhD/D.Ed./MSc Research projects the supervisor must be listed as Principal Investigator.*Doctoral researchers and Research Masters may be listed as Principal Investigators, depending on the conventions of the discipline and on the individual case. It should be made clear, in subsequent sections of this application, who is carrying out the research procedures.*

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| *NAME* | *SCHOOL/UNIT* | *EMAIL* |
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**OTHER INVESTIGATORS:**

|  |  |  |
| --- | --- | --- |
| *NAME* | *SCHOOL/UNIT* | *EMAIL* |
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**1.2 WILL THE RESEARCH BE UNDERTAKEN ON-SITE AT DUBLIN CITY UNIVERSITY?**

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| **YES or NO** |
| **…** |

**If NO, state details of the off-campus location – provide details of the approval to gain access to that location in section 2.7***.*

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**1.3 WILL THIS RESEARCH INVOLVE ANIMALS?**

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| **YES or NO** |
| **…** |

**If YES, please provide details on the outcome from BRAG and attach copies of approval(s) received etc.**

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**1.4 HAS THIS RESEARCH PROPOSAL BEEN SUBMITTED TO ANOTHER ETHICS COMMITTEE?**

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| **YES or NO** |
| **…** |

**If YES, please provide details on the outcome and attach copies of approval(s) received etc.**

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**1.4.1 HAS THIS RESEARCH PROPOSAL BEEN REFUSED ETHICAL APPROVAL FROM THIS OR ANOTHER RESEARCH ETHICS COMMITTEE PREVIOUSLY?**

**If YES, please provide details.**

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**DECLARATION BY PRINCIPAL INVESTIGATOR(S)**

*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 guidelines*](https://www.dcu.ie/researchsupport/ethicsapproval)*,* *the University’s* [*Conflict of Interest Policy*](https://www.dcu.ie/media/48901)*, its* [*Code of Good Research Practice*](https://www.dcu.ie/media/38111) *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.*

*If there exists any affiliation or financial interest for researcher(s) in this research or its outcomes or any other circumstances which might represent a perceived, potential or actual conflict of interest this should be declared in accordance with the University’s* [*Conflict of Interest Policy*](https://www.dcu.ie/media/48901)*.*

*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. Supervisor(s) signature(s) is / are required as evidence that they have read and approve this submission.*

***Please note:***

1. *Any amendments to the original approved proposal must receive prior REC approval.*
2. *As a condition of approval investigators are required to document and report immediately to the Secretary of the Research Ethics Committee any adverse events, any issues which might negatively impact on the conduct of the research and/or any complaint from a participant relating to their participation in the study.*

***Electronic Signature(s):***

*Principal investigator(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

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

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

***I, the main supervisor of this research proposal, have read and approve this submission.***

*Supervisor(s) signature (where relevant):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

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

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

**2. PROJECT OUTLINE**

**2.1 LAY DESCRIPTION, AIMS & JUSTIFICATION, METHODOLOGY** *(Approx.900 words)*

*Please outline, in terms that any non-expert would understand, what your research project is about, including what participants will be required to do. Please explain any technical terms or discipline-specific phrases. State the aims and significance of the project. Where relevant, state the specific hypothesis to be tested. Please provide a brief description of background research, a justification as to why this research project should proceed in that context and an explanation of any expected benefits to the community.* ***NB*** *– all references cited should be listed in an attached bibliography. Provide an outline of the proposed method and state who is doing which task – include details of data collection techniques, the tasks participants will be asked to do, the estimated time commitment involved, and how data will be analysed. If the project includes any procedure which is beyond already established and accepted techniques, please include a description of it. There should be enough detail provided to facilitate ethical review, but applicants are encouraged to keep it as succinct as possible.*

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***2.2* INVESTIGATORS’ QUALIFICATIONS, EXPERIENCE AND SKILLS (Approx. 200 words)**

*List the academic qualifications and outline the experience and skills relevant to this project that the PI, other researchers and any supporting staff have in carrying out the research and in dealing with any emergencies, unexpected outcomes, or contingencies that may arise.* ***State specifically who will be carrying out the research procedures.***

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**2.3 PARTICIPANT PROFILE**

*List and very briefly describe each participant group where applicable. For instance, participant group 1 will consist of…, participant group 2 will consist of… etc.* *Provide the number, age range and source of participants. Please provide a justification of your proposed sample size.*

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**2.4 PARTICIPANT RECRUITMENT**

*Please provide specific details as to how you will be recruiting participants. How will people be informed that you are doing this research? How will they be approached and asked if they are willing to participate? If you are mailing or phoning people, please explain how you have obtained their names and contact details. If a recruitment advertisement is to be used, please ensure you attach a copy to this application (Approx. 100 words).*

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**2.5 IS IT LIKELY THAT ANY PARTICIPANTS COULD BE CONSIDERED POTENTIALLY VULNERABLE?**

*Are some or all participants vulnerable in any way? (e.g. by virtue of the group they belong to, people who have undergone traumatic or adverse emotional events, people with diminished cognitive ability, power relations between researchers and participants etc.)?*

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| **YES or NO** |
| **…** |

*If Yes, please state and describe what this vulnerability (or vulnerabilities) is and justify why this research is being done with such participants*

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**2.6 WILL THE IDENTITY OF THE PARTICIPANTS BE PROTECTED?**

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| **YES or NO** |
| **…** |

If NO, please explain why

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**IF YOU ANSWERED YES TO 2.6, PLEASE ANSWER THE FOLLOWING QUESTION:**

**2.7 HOW WILL THE ANONYMITY OF THE PARTICIPANTS BE RESPECTED?**

*Please bear in mind that where the sample size is very small, it may be impossible to guarantee anonymity/confidentiality of participant identity. Participants involved in such projects need to be advised of this limitation in the Plain Language Statement/Information Sheet. If you intend to fully anonymize the data, please provide details.*

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**2.8 LEGAL LIMITATIONS TO DATA CONFIDENTIALITY**

*Participants need to be made aware that confidentiality* *of information provided cannot always be guaranteed by researchers and can only be protected within the limitations of the law - i.e., it is possible for data to be subject to subpoena, freedom of information claim or mandated reporting by some professions. This information should be included in your Plain Language Statement and Informed Consent Form. Depending on the research proposal and academic discipline, you may need to state additional specific limitations.*

State how and where participants will be informed of these limitations.

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**2.9 CHILD PARTICIPANTS (anyone under 18 years old)**

*If your participants include children, you* ***must*** *confirm that you are in compliance with the research specific guidelines as detailed in* [*Keeping Children Safe - Policies and Procedures supporting Child Protection at DCU*](https://www.dcu.ie/system/files/2020-09/157-child_protection_handbook_rev121.pdf)*.*

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| ***Please indicate your compliance with the following guidelines:*** | **Mark here** |
| We confirm that we have read and agree to act in accordance with the DCU Child Protection policy and procedures |  |
| 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) |  |

**2.10 PLEASE EXPLAIN WHEN, HOW, WHERE, AND TO WHOM RESULTS WILL BE DISSEMINATED, INCLUDING WHETHER PARTICIPANTS WILL BE PROVIDED WITH ANY INFORMATION AS TO THE FINDINGS OR OUTCOMES OF THE PROJECT*?***

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**2.11 ARE OTHER APPROVALS REQUIRED TO GAIN ACCESS TO ANOTHER LOCATION, ORGANISATION, SCHOOL ETC.?**

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| **YES or NO** |
| **…** |

If YES, please specify from whom and attach a copy of the approval documentation. If this is not yet available, please explain when this will be obtained.

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**3. RISK AND RISK MANAGEMENT**

**3.1 EXPLAIN AND JUSTIFY THE STATED LEVEL OF RISK TO PARTICIPANTS**

*You must provide a justification for the stated level of risk and its corresponding level of review (Full Committee, Expedited, Notification), as indicated on the cover page of your application. Note that the level of risk may be influenced by the vulnerability of the research group, the methods employed and the nature of the research itself. For further information on risk levels, please refer to the Levels of Review information on the* [*Research Support Services website*](https://www.dcu.ie/researchsupport/researchethics.shtml)*.*

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**3.2 POTENTIAL RISKS TO PARTICIPANTS AND RISK MANAGEMENT PROCEDURES**

*Identify, as far as possible, all potential risks to participants (physical, psychological, social, legal, economic, etc.), associated with the proposed research. Will your research involve deception, investigation of participants involved in illegal activities, performance of any acts which might diminish the self-esteem of participants or cause them to experience embarrassment, regret or depression, administration of any substance or agent, collection of body tissues or fluid samples, use of non-treatment of placebo control conditions, collection and/or testing of DNA samples,* *administration of ionising radiation? Please explain what risk management procedures will be put in place to minimise these risks.*

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**3.3 ARE THERE LIKELY TO BE ANY BENEFITS (DIRECT OR INDIRECT) TO PARTICIPANTS FROM THIS RESEARCH?**

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| **YES or NO** |
| **…** |

If YES, provide details

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**3.4 ARE THERE ANY SPECIFIC RISKS TO RESEARCHERS?**

*Examples include use of dangerous materials, asking certain types of questions, research being undertaken in certain locations, researchers working alone in isolated areas, etc.*

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| **YES or NO** |
| **…** |

If YES, please describe and explain what risk management procedures will be put in place to minimise these risks

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**3.5 DEALING WITH ADVERSE / UNEXPECTED OUTCOMES**

*Please describe what measures/protocols you have put in place in the event that there are any unexpected outcomes or adverse effects to participants arising from involvement in the project.*

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**3.6 SUPPORT FOR PARTICIPANTS**

*Depending on risks to participants you may need to consider having additional support for participants during/after the study. Consider whether your project would require additional support, e.g., external counselling available to participants. Please advise what support will be available.*

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**3.7 HOW WILL THE CONDUCT OF THE PROJECT BE MONITORED?**

*Please explain how the principal investigator will monitor the conduct of the project (especially where several people are involved in recruiting or interviewing, administering procedures, etc.) to ensure that it conforms to the procedures set out in this application. In the case of student projects please give details of how the supervisor(s) will monitor the conduct of the project.*

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**3.8 DO YOU PROPOSE TO OFFER PAYMENTS OR INCENTIVES TO PARTICIPANTS?**

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| **YES or NO** |
| **…** |

If YES, please provide further details

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**3.9 DO ANY OF THE RESEARCHERS ON THIS PROJECT HAVE A PERSONAL, PHILOSOPHICAL, FINANCIAL, POLITICAL, IDEOLOGICAL, OR COMMERCIAL INTEREST IN ITS OUTCOME THAT MIGHT INFLUENCE THE INTEGRITY OF THE RESEARCH, OR BIAS THE CONDUCT OR REPORTING OF THE RESEARCH, OR UNDULY DELAY OR OTHERWISE AFFECT THEIR PUBLICATION?**

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| **YES or NO** |
| **…** |

If YES, please specify how this conflict of interest will be addressed

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**4. PERSONAL DATA**

**Definition of Personal Data**

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. Typical examples of personal data in a research context are:

a) paper based records e.g. research participant files, patient records, consent declarations, interview notes etc.

b) electronic records e.g. database of participant details, online survey returns, photos, audio & visual recordings, IP addresses, diagnostic / clinical imaging etc.

c) other e.g. genetic data, biometric data, clinical or medical samples etc.

Note: Any data that is fully and completely anonymous is not considered to be personal data.

**Further information on data protection is available from the University’s** [**Data Protection Unit**](https://www.dcu.ie/ocoo/data-protection)**. In addition, you should also consider consulting with your Unit’s** [**GDPR Advocate**](https://www.dcu.ie/ocoo/data-protection-policies-guides-protocols-and-templates) **for help and advice on filling out this section of the form.**

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| **(A) Your knowledge of Data Protection** |
| Have you completed the online GDPR **‘2020 Data Protection Staff’** module on Loop which is available to all staff of the University? | **YES or NO** |  **….** |

If you answered ‘No’ to the previous question then the DCU Data Protection Unit (DPU) strongly recommends that all applicants complete the training module on Loop before completing this section of the REC Application Form.

The Loop training module can be accessed at this[**link**](https://loop.dcu.ie/course/view.php?id=44556)and searching for ‘2020 Data Protection Staff’. If you experience difficulties in doing so please contact the [Teaching Enhancement Unit](https://www.dcu.ie/teu/get-in-touch) for assistance.

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| **(B) Initial Assessment – Is the data to be used actually personal data?** ***Rationale: Not all data used in a research project can be defined as ‘Personal Data’*** |
| **1** | Will the proposed research include living human subjects?*Rationale – personal data applies only to living individuals.* | **YES or NO** | **….**  |
| **2** | Will the proposed research use any data that can be linked to an identified, or an identifiable, person? *Rationale – to be personal data it must be possible to associate it with a person.* | **YES or NO** | **….**  |
| **3** | Will the proposed research use any data identifiers that can be linked to a person? E.g. a participants name, code or ID number, their address, their IP address etc.*Rationale – fully anonymised data is not personal data.* | **YES or NO**  | **….**  |

If you answered ‘Yes’ to any of the questions 1 to 3 in sub-section (B), then continue to sub-section (C) and answer questions 1-9.

If you answered ‘No’ to all of the questions 1 to 3 in sub-section (B), then skip sub-section (C) and proceed section 5 of form.

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| **(C) Assessing the degree of risk inherent in the personal data** |
| **1** | Will the proposed research involve the use of personal data on individuals which reveals any of the following attributes or characteristics about them? (State ‘Yes’ or ‘No’ as appropriate to all of the following) |  |  |
|  | *Racial or ethnic origin* | **YES or NO** | **….**  |
|  | *Political opinions* | **YES or NO** | **….**  |
|  | *Religious or philosophical beliefs* | **YES or NO** | **….**  |
|  | *Trade union membership* | **YES or NO** | **….**  |
|  | *Genetic data* | **YES or NO** | **….**  |
|  | Biometric data | **YES or NO** | **….**  |
|  | *Data concerning health* | **YES or NO** | **….**  |
|  | *Data concerning a person's sex life or sexual orientation* | **YES or NO** | **….**  |
| **2** | Will the proposed research involve the use of personal data relating to children or vulnerable individuals? *A child, for data protection purposes, is defined as an individual below 18 years of age. Where the processing relates to ‘electronic marketing’ the age limit is reduced to 16 years. A vulnerable individual may be anyone who is unable to consent to, or to oppose, the processing of his or her data for any reason, including disability.* | **YES or NO** | **….**  |
| **3** | Will the proposed research involve the use of data relating to an individual’s criminal convictions and / or offences? | **YES or NO** | **….**  |
| **4** | Will the proposed research involve the large-scale processing of personal data? *This may include: a wide range or large volume of personal data; processing which takes place over a large geographical area; processing where a large number of people are affected (e.g. over 100 individuals); or where the processing is extensive or has long-lasting effects.*  | **YES or NO** | **….**  |
| **5** | Will the proposed research involve any form of automated processing of personal data? *In particular, to analyse or predict aspects concerning that person's performance at work, economic situation, health, personal preferences, interests, reliability, behaviour, location or movements.* | **YES or NO** | **….**  |
| **6** | Will the proposed research involve sharing or transferring any personal data to a 3rd party outside of DCU? *For example other research partners, providers of translation or transcription services, etc.* | **YES or NO** | **….**  |
| **7** | Will the proposed research require the sharing or processing of personal data outside the EU or the EEA? *The EEA is the European Economic Area (i.e. the EU plus Norway, Liechtenstein and Iceland)* | **YES or NO** | **….**  |
| **8** | Will the proposed research involve the matching or combining of separate datasets of information on individuals in a way that would exceed their reasonable expectations of privacy? *An example would be combining mobile phone location data along with any other dataset to identify individuals.* | **YES or NO** | **….**  |
| **9** | Will it be possible to fully anonymise (as opposed to merely pseudo-anonymising) the personal data before it is obtained and used by you in the proposed research? *This might occur if the data is provided to you by an external organisation or another educational institution as part of a collaborative study.* *Anonymised data is not personal data. Anonymisation is the process of removing personal identifiers, both direct and indirect, that may lead to an individual being identified.* *Pseudonymisation is the processing of personal data in such a manner that the personal data can no longer be attributed to a specific living individual without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure its security.* | **YES or NO** | **….**  |

**Important Point: Next Step**

If you answered ‘Yes’ to one or more of the questions 1 to 9 in sub-section (C) **you must contact the** [**Data Protection Unit (DPU)**](https://www.dcu.ie/ocoo/data-protection) **prior to submitting this application form to the REC**. The DPU will assess whether there are any further data protection issues to be addressed or additional procedures to be followed.

**5. DATA / SAMPLE STORAGE, SECURITY AND DISPOSAL**

*For the purpose of this section the term ‘Data’ includes personal data that is in a raw or a processed state (e.g. interview audiotape, transcript or analysis, etc.). The term ‘Samples’ include body fluids and/or tissue samples.*

**5.1 HOW AND WHERE WILL THE DATA / SAMPLES BE STORED?**

 *DCU recommends that any data stored electronically offsite should utilise the DCU Google Drive. Alternative offsite storage will need to be justified and must meet data protection and GDPR compliance requirements.*

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**5.2 WHO WILL HAVE ACCESS TO DATA / SAMPLES?**

*If people other than the main researchers have access, please name who they are and explain for what purpose.*

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**5.3 HOW LONG IS THE DATA TO BE HELD OR RETAINED?**

*Note that, with very few exceptions,* ***Personal Data*** *may not be retained indefinitely. It is up to the research team to establish an upper retention limit for each category of Personal Data used within the project and to ensure it is applied at the expiry of that limit.*

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**5.4 WILL THE PERSONAL DATA BE USED AT A LATER DATE FOR THE PURPOSE OF PUBLICATION OF THE RESULTS OF THE RESEARCH?**

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| **YES or NO** |
| **…** |

*Where it is intended that the personal data used in the project will be used at a later date for the purposes of publication please explain how consent to do so will be obtained.*

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**5.5 IF THE DATA/SAMPLES ARE TO BE DISPOSED OF AT THE END OF THE PROJECT PLEASE EXPLAIN HOW, WHEN AND BY WHOM THIS WILL BE DONE?**

*Note that simply deleting files is not sufficiently secure. The additional steps to be taken to maintain data security should be given.* ***Personal data*** *must be disposed of in a safe and secure manner at the end of its retention period. If the data is stored in (a) a paper-based format, then shredding or disposal via a secure bin is recommended; or (b) in an electronic-based format, then deletion of the record or the full anonymization of the data is recommended. If data/samples are* ***not*** *being disposed of, please justify that intention.*

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| **How will the data/samples be disposed?** Please describe the means by which the personal data will be deleted or destroyed. This includes personal data held in hard copy and digital formats. |  |
| **When will the data/samples be disposed?** Please indicate the intended retention period of the personal data, and reasons for this retention period. Please note that retention periods must be GDPR compliant and must be consistent with the [DCU Retention Policy**.**](https://www.dcu.ie/sites/default/files/policy/182_-_data_retention_v1.pdf) |  |
| **By whom will the data/samples be disposed?** Please indicate the designated team member(s) with responsibility for deletion and/or destruction of the research project’s personal data. |  |

**6. FUNDING OF THE RESEARCH**

**6.1 HOW IS THIS WORK BEING FUNDED?**

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**6.2 PROJECT GRANT NUMBER** *(If relevant and/or known – otherwise mark as N/A)*

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**6.3 DOES THE PROJECT REQUIRE APPROVAL BEFORE CONSIDERATION FOR FUNDING BY A GRANTING BODY?**

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| **YES or NO** |
| **…** |

**6.4 HOW WILL PARTICIPANTS BE INFORMED OF THE SOURCE OF THE FUNDING?** *(E.g. included in the Plain Language Statement)*

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**6.5 DO THE FUNDERS OF THIS PROJECT HAVE A PERSONAL, FINANCIAL, POLITICAL, IDEOLOGICAL, OR COMMERCIAL INTEREST IN ITS OUTCOME THAT MIGHT COMPROMISE THE INDEPENDENCE AND INTEGRITY OF THE RESEARCH, OR BIAS THE CONDUCT OR REPORTING OF THE RESEARCH, OR UNDULY DELAY OR OTHERWISE AFFECT THEIR PUBLICATION?**

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| **YES or NO** |
| **…** |

If YES, please specify how this conflict of interest will be addressed

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**7. PLAIN LANGUAGE STATEMENT** *(Attach to this document. Approx. 400 words)*

*A Plain Language Statement (PLS) should be used in all cases. This is written information in plain language that you will be providing to participants, outlining the nature of their involvement in the project and inviting their participation. The PLS should specifically describe what will be expected of participants, the risks and inconveniences for them, and other information relevant to their involvement. Please note that the language used must reflect the participant age group and corresponding comprehension level– if your participants have different comprehension levels (e.g. both adults and children) then separate forms should be prepared for each group. The PLS can be embedded in an email to which an online survey is attached, or handed/sent to individuals in advance of their consent being sought. See the link to sample templates on the* [*Ethics Approval section*](https://www.dcu.ie/researchsupport/ethicsapproval) *of the Research Support Services website****.***

**PLEASE CONFIRM WHETHER THE FOLLOWING ISSUES HAVE BEEN ADDRESSED IN YOUR PLAIN LANGUAGE STATEMENT/ INFORMATION SHEET FOR PARTICIPANTS:**

|  |  |
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|  | **YES or NO** |
| Introductory Statement (PI and researcher names, school, title of the research) |  |
| What is this research about? |  |
| Why is this research being conducted? |  |
| What will the participant be expected to do/have to do if they decide to participate in the research study? |  |
| How will their privacy be protected? |  |
| How will the data be used and subsequently disposed of? |  |
| What are the legal limitations to data confidentiality? |  |
| Are there any benefits of taking part in the research study? |  |
| Are there any risks of taking part in the research study? |  |
| Confirmation that participants can change their mind at any stage and withdraw from the study |  |
| How will participants find out what happens with the project? |  |
| Contact details for further information (including REC contact details) |  |
| Details relating to GDPR Compliance where Personal Data is being sought |  |

If any of these issues are marked NO, please justify their exclusion:

|  |
| --- |
|  |

**8. INFORMED CONSENT FORM** *(Attach to this document. Approx. 300 words)*

*In most cases where interviews or focus groups are taking place, an Informed Consent Form is required. This is an important document requiring participants to indicate their consent to participate in the study and give their signature. In cases where an anonymous questionnaire is being used, it is not enough to include a tick box in the questionnaire. Participants should indicate their consent to each aspect of the research in a staged manner by checking mandatory checkboxes.*

*See link to sample templates on the* [*Ethics Approval section*](https://www.dcu.ie/researchsupport/ethicsapproval) *of the Research Support Services website.*

**NB – IF AN INFORMED CONSENT FORM IS NOT BEING USED, THE REASON FOR THIS MUST BE JUSTIFIED HERE.**

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**9. ASSENT FORM & PLAIN LANGUAGE STATEMENT FOR CHILDREN** *(Attach to this document.)*

*A child specific Plain Language Statement (PLS) should be used in research where children will be involved. The PLS must be written in a way that is understandable for children within your targeted age group. It also must state, in plain language, the nature of their involvement in the project and inviting their participation. The PLS should specifically describe what will be expected of participants, the risks and inconveniences for them, and other information relevant to their involvement. In addition, child participants should also be provided with an Assent Form. Parents/guardians will be provided with the Informed Consent Form, but each child should provide assent before taking part in the research. The Assent Form needs to be understandable to the age-group you are targeting. See link to sample templates on the* [*Ethics Approval Section*](https://www.dcu.ie/researchsupport/ethicsapproval) *of the Research Support Services website.*

**NB – IF AN ASSENT FORM IS NOT BEING USED, THE REASON FOR THIS MUST BE JUSTIFIED HERE.**

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**10. SUBMISSION CHECKLIST** *(Attach to this document)*

**Please confirm that all supplementary information is included in your application (in electronic copy). If questionnaire or interview questions are submitted in draft form, please indicate this by putting (draft) after YES. A copy of the final documentation must be submitted for final approval when available.**

|  |  |  |
| --- | --- | --- |
| **My application has been collated as one electronic file which includes the following documentation:** | **INCLUDED****(mark as YES)** | **NOT APPLICABLE (mark as N/A)** |
| Bibliography |  |  |
| Recruitment advertisement |  |  |
| Plain language statement/Information Statement |  |  |
| Informed Consent form |  |  |
| Informed Assent form  |  |  |
| Evidence of external approvals related to the research |  |  |
| Questionnaire / Survey |  |  |
| Interview / Focus Group Questions |  |  |
| Debriefing material |  |  |
| Other (e.g. BSC approval review letter, Data Protection Impact Assessment) |  |  |

# DUBLIN CITY UNIVERSITY

**Sample Template – Plain Language Statement (approx. 400 words)**

#### *A Plain Language Statement (PLS) should use language that reflects the participant age group and corresponding comprehension level. It should contain the following information. The headings are there for guidance and do not need to be included in your form*.

#### Introduction to the Research Study

#### *Identify the Research Study Title, the university department involved, the principal investigator (including his/her DCU contact details) and any other investigators*

**Privacy Notice**

*An appropriate Privacy Notice is the means by which data subjects are informed about the use of their data. If personal data is being collected and processed, please refer to the University’s* [*Data Protection Unit*](https://www.dcu.ie/ocoo/data-protection-policies-guides-protocols-and-templates) *website for advice and include the following information in the PLS:*

* *The identity of the Data Controller (or in some cases the Joint Data Controllers) plus the details of any Data Processor (where applicable) should be clearly stated on the PLS. The Data Controller will nearly always be DCU (where the researcher is a DCU researcher). The PLS should also state the name of the research project and the identity of the particular School / Unit of DCU from which it originates.* *A Data Processor may hold or process personal data but does not exercise responsibility for or control over the personal data, for example, a transcription service, or a software or cloud hosting company.*
* *The identity of the DCU Data Protection Officer – Mr. Martin Ward (**data.protection@dcu.ie* *Ph.: 7005118 / 7008257)*
* *The purpose of the data processing i.e. the reasons why the data is being requested and the purpose to which it will be applied.*
* *The reason(s) for which the data will be processed or held.*
* *The categories or types of personal data to be processed.*
* *The details of any third parties (i.e. data processors) with whom the data will be shared or transferred, and the reasons for sharing.*
* *The details of any external (i.e. non-DCU) parties with whom the data will be shared or transferred, and the reasons for sharing.*
* *Where relevant, details of any intention to transfer the data to other countries, especially if outside of the EEA (European Economic Area), and the legal basis invoked for such transfers.*
* *The data’s retention period or the criteria used to determine retention periods.*
* *The right of the individual to lodge a complaint with the* [*Irish Data Protection Commission*](https://www.dataprotection.ie/)*.*
* *Information on the rights of the data subject - Individuals’ have the right to access their own personal data and PLS should inform them how to do this and who to contact either within the research team, or alternatively by contacting the Data Protection Unit.*
* *Information on their rights to withdraw consent (if invoked) and who to contact to withdraw consent.*
* *If it is intended that the data be used for future studies, you must specify the general parameters of the future further research uses to which the participant’s personal data may be used.*
* *In cases where personal data will later be anonymized (e.g. for statistical or aggregated data), it is best practice to describe this, so that the participant is fully informed.*

**Statement as to whether or not the research data is to be destroyed after a minimum period**

*Clearly state (if applicable) when data will be destroyed or fully anonymized after the end of the research project.*

**Details of what participant involvement in the Research Study will require**

*E.g., involvement in interviews; completion of questionnaire; audio/video-taping of events, and the estimated time commitment for the activities*

**Potential risks to participants from involvement in the Research Study (if greater than that encountered in everyday life)**

**Any benefits (direct or indirect) to participants from involvement in the Research Study**

**Advice as to arrangements to be made to protect confidentiality of data, including that confidentiality of information provided is subject to legal limitations**

*Participants need to be made aware that confidentiality* *of information provided cannot always be guaranteed by researchers – please include the following statement:*

*“Confidentiality of information can only be protected within the limitations of the law - i.e., it is possible for data to be subject to subpoena, freedom of information claim or mandated reporting by some professions”.*

*Depending on the research proposal and academic discipline, you may need to state additional specific limitations.*

**Statement that involvement in the Research Study is voluntary**

*State that participants may withdraw from the Research Study at any point. You should explain to the participant that their participation in the project will end, at the point they withdraw, and refer back to the data protection/privacy notice as to what will happen regarding their data. For example, withdrawing consent may mean that no future data collection will take place but previously collected data will still be processed etc.*

**Any other relevant information – e.g.**

* *if the sample size is small, advice to participants that this may have implications for privacy / anonymity.*
* *if participants are in a dependent relationship with any of the researchers, a clear statement that their involvement / non-involvement in the project will not affect their ongoing assessment / grades / management.*

A Plain Language Statement must end with the following statement:

*If participants have concerns about this study and wish to contact an independent person,*

*please contact:*

## The Secretary, Dublin City University Research Ethics Committee, c/o Research and Innovation Support, Dublin City University, Dublin 9. Tel 01-7008000, e-mail rec@dcu.ie

# DUBLIN CITY UNIVERSITY

**Sample Template – Informed Consent Form (approx. 300 words)**

#### *An Informed Consent Form should generally contain the information detailed below. It should be written in the first person, e.g. “I will be asked to attend…I may withdraw from the research study at any point…..I am aware that the data…etc.” The headings are there for guidance and do not need to be included in your form.*

#### Research Study Title

#### *Also identify the school / centre involved, the principal investigator and any other investigators.*

**Clarification of the purpose of the research**

*If personal data is being collected and processed, please ensure that the participants acknowledge the identity of the data controller and the purpose(s) of the processing for which the personal data are intended.*

**Confirmation of particular requirements as highlighted in the Plain Language Statement**

*Requirements may include involvement in interviews, completion of questionnaire, audio / video-taping of events etc.. Getting the participant to acknowledge requirements is preferable, e.g.*

*Participant – please complete the following (Circle Yes or No for each question)*

*I have read the Plain Language Statement (or had it read to me) Yes/No*

*I understand the information provided Yes/No*

*I understand the information provided in relation to data protection Yes/No*

*I have had an opportunity to ask questions and discuss this study Yes/No*

*I have received satisfactory answers to all my questions Yes/No*

*I am aware that my interview will be audiotaped Yes/No*

**Confirmation that involvement in the Research Study is voluntary**

*E.g. I may withdraw from the Research Study at any point.*

**Confirmation of arrangements to be made to protect confidentiality of data, including that confidentiality of information provided is subject to legal limitations**

**Confirmation of arrangements regarding the retention / disposal of data**

**Confirmations relating to any other relevant information as indicated in the PLS**

*E.g.**I consent to the use of my data for future studies within the following parameters (provide detail)*

**Signature:**

I have read and understood the information in this form. My questions and concerns have been answered by the researchers, and I have a copy of this consent form. Therefore, I consent to take part in this research project

 **Participants Signature:**

 **Name in Block Capitals:**

 **Witness:**

 **Date:**

**Anonymous Online Consent Form Template**

#### *In cases where an anonymous questionnaire is being used, researchers are required to provide a separate tick box for each statement that the participant is being asked to consent to / acknowledge. Each statement must be included as an essential field in order to ensure that full informed consent has been obtained (see example below).*

#### *An Informed Consent Form should generally contain the information detailed below. It should be written in the first person, e.g. “I will be asked to attend…I may withdraw from the research study at any point…..I am aware that the data…etc.” The headings are there for guidance and do not need to be included in your form.*

#### Research Study Title

#### *Also identify the school / centre involved, the principal investigator and any other investigators.*

**Clarification of the purpose(s) of the research**

**Confirmation of particular requirements as highlighted in the Plain Language Statement**

*Getting the participant to acknowledge the requirements is mandatory. Participants should not be able to access the survey until they have agreed to all items and indicated their consent. e.g.*

**Example:**

*Participant – please complete the following (by clicking Yes/No for each question)*

