***Taught Masters Research Ethics Committee – School of Education***

***TMREC-EDU***

***Human Subjects Low Risk Study Review Form***

***(exempt from a full committee review)***

*Depending on the nature of the study described below your study may require a preliminary review by the TMREC and may be subject to further clarification.* ***Please note that all questions requiring either a ‘yes’ or ‘no’ answer must be completed –if you fail to do so, or leave them blank, your form will be returned.***

***Please do not alter the format of this form and submit it as a word document only***

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| ***NOTE ON INSURANCE The HREC is no longer responsible for overseeing insurance requirements.*** |
| *Applicants should refer to* <https://www.ucd.ie/sirc/insurance/humanresearchinsurance/>  *for information on insurance for human research. It is the student’s responsibility to ensure that the appropriate insurance cover is in place for their research. This should be done via the mandatory self-assessment checklist which can be found at the linked location.* |

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| ***NOTE ON FACE-TO FACE INTERACTIONS WITH PARTICIPANTS*** |
| *If your study involves face-to-face interactions with participants, including UCD students, applicants should refer to* [*https://www.ucd.ie/sirc/coronavirus/returntocampusworking/*](https://www.ucd.ie/sirc/coronavirus/returntocampusworking/) *and complete the* ***Human Research Ethics Risk Assessment.***  *Please follow the instructions in the template.* |

**Section A: General Information**

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| 1. ***CRITERIA FOR LOW-RISK REVIEW******please select one or more criteria by indicating ‘yes’ or ‘no’ in the boxes provided – failure to complete this section correctly will mean that your submission will be returned to you.*** | | |
| ***I am submitting a low risk/exemption for the study summarised below, on the basis that*** this research protocol is **low risk** and meets one or more of the criteria for exemption from review as detailed below. *(select Yes or No)* | ***Yes*** | ***No*** |
| 1. All aspects of the protocol have received ethical approval from another REC in an approved body (e.g. National Research Ethics Committee [NREC], Hospitals, hospices, prisons, health authorities). **If yes,** *you need only* *provide details in Section C Question 8 below and provide a pdf copy of that approval. Other sections need not be filled out.* |  |  |
| 1. the study has been reviewed and approved by a recognised REC but is using participants from UCD.   **If yes,** *provide details in Section C Question 8 below and provide a pdf copy of that approval.* |  |  |
| 1. using participants from UCD for anonymous surveys on non-sensitive issues |  |  |
| 1. Accessing UCD Students for non-sensitive, pooled and de-identified information on student performance in modules/courses/project evaluations that will be used for research purposes |  |  |
| 1. Standard Educational Practices |  |  |
| 1. Standard Psychological tests |  |  |
| 1. Anonymous surveys |  |  |
| 1. Interviews with non-vulnerable participants |  |  |
| 1. Research involving persons elected to/candidates for public office –speaking in professional capacity |  |  |
| 1. Public observation (you may need to provide permissions from external organisations) |  |  |
| 1. Research which uses only existing data/secondary data and is either publicly available or available upon request |  |  |
| 1. The study involves a non-sensitive topic |  |  |
| 1. Other |  |  |

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| 1. ***ACCESS TO UCD STUDENTS FOR RESEARCH PURPOSES ONLY*:** *please tick yes or no – do not leave blank* | | | | | |
| **Are you seeking permission to access UCD Students from one school*?*** *If yes, please ensure that you have permission from the head of that school before approaching participants?* | | **Are you seeking permission to access UCD Students from more than one school?** *If yes, do you have permission from the head of those schools?* | | **Are you seeking permission to conduct a university-wide survey of UCD students?** *(if the research is a campus-wide student survey[[1]](#footnote-1)* ***and*** *involves students from two or more schools, then permission to schedule the survey should be sought from the University Student Survey Board (USSB) after the ethical review and approval has been granted) To book a time slot for the survey please contact* [*ussb@ucd.ie*](mailto:ussb@ucd.ie) | |
| **Yes** | **No** | **Yes** | **No** | **Yes** | **No** |
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| 1. ***PROJECT DETAILS*** | | | | | |
| **3a)** | **Project Title:** |  | | | |
| **3b)** | **Proposed Study Start Date:**  **(dd/mm/yy)** | | **Proposed Study Completion Date:**  **(dd/mm/yy)** | **Proposed Start Date of Data Collection:**  **(dd/mm/yy)** | **Proposed Completion Date of Data Collection:**  **(dd/mm/yy)** |
|  | |  |  |  |

*NOTE: Approval will not be granted if recruitment and/or data collection has already begun – there are no retrospective approvals*

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| 1. ***APPLICANT DETAILS***  *Mandatory – all question must be completed fully* | | | | | | | | | |
| **4a)** | **Name of Applicant** *(please include title if applicable):* |  | | | | | | | |
| **4b)** | **Applicant’s position in UCD** *(please put ‘yes’ in relevant space):* | **Academic** | | | **Postgraduate** | | | | **Other** |
| **Staff** | | **Post Doc** | ***PhD*** | ***Research Masters*** | | ***Taught Masters?*** |  |
|  | |  |  |  | |  |
| **4c)** | **Applicant’s UCD Contact Details** | **UCD Email** *(UCD email addresses, no student numbers or external addresses)* | | | | | | | |
|  | | | | | | | |
| **4d)** | **UCD School** *If it is not clear the form will be returned* |  | | | | | | | |
| **4e)** | **Funding** *if applicable* | **Source** |  | | | | **Amount** | **€** | |

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| 1. ***SUPERVISOR DETAILS*** *(if applicable)* ***& INTERNAL/EXTERNAL/ORG DETAILS*** *(if applicable) name all investigators on project* | | | | |
| **5a) Supervisor’s Name** *(including title e.g. Prof., Dr. other etc.,)* |  | **UCD Telephone:** | | **UCD Email:** |
| **5b) UCD Investigator(s) and affiliations** | *(name all investigators on project)* | | | |
|  | | | |
| **5c) External Investigator(s) Name** *if applicable* |  | | | |
| **5d) Name & Address of external Organization** *if applicable* |  | | | |
| **5e)** **What is the relationship between the UCD investigators, the external investigators and the project?** |  | | | |
| **5f)** **Do you have a Data Sharing and Data Management Agreement in place** with the external investigator(s) and or external organisation? *if applicable* | | | **Yes** | **No** |
|  |  |
| **5g)** if yes, **Describe briefly the Data Sharing and Data Management Agreement** |  | | | |
| **5h) Are any of the External Investigators involved with the engagement of Patients or the Public (not as participants) in any aspect of the execution of the research?** |  | | | |

**Section B: Research Design & Methodology**

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| 1. ***RESEARCH PROPOSAL*** *If this section is not completed correctly the form will be returned* | | | | | | | |
| **6a) Methods of data collection** | | | ***Yes*** | ***No*** | *(select the appropriate box and provide brief details to ‘Yes’)* | | |
| i | | standard educational practices |  |  |  | | |
| ii | | standard educational tests |  |  |  | | |
| iii | | standard personality tests |  |  |  | | |
| iv | | standard psychological tests |  |  |  | | |
| v | | interviews or focus groups |  |  |  | | |
| vi | | public observations |  |  |  | | |
| vii | | persons in public office |  |  |  | | |
| viii | | using existing data only |  |  |  | | |
| ix | | surveys/questionnaires |  |  |  | | |
| x | | audio/video recordings |  |  |  | | |
| xi | | other *(please specify)* |  |  |  | | |
| **6b) Who are the participants?** *(including size and composition*) | | |  | | | | |
| **6c) Where are you recruiting the participants from?** | | |  | | | | |
| i | | Do you have permission to access these participants? *provide details of organization/group and attached a copy of the permission if applicable* |  | | | | |
| *You will need to provide proof of permission from directors of organisations, principals of schools, and the relevant authority of any other type of body where you are seeking to access participants in their care* | | | | | | | |
| **6d) How will you obtain informed consent? Yes or no?** | | | **Written** | | | **Oral** | **Audio** |
|  | | |  |  |
| i | Which of these documents will you be using? **Yes or no?** | | **Information Sheet** | | | **Consent Form** | **Survey/Questionnaire** |
|  | | |  |  |
| **6e) Aims and Objectives of the study** *(in brief lay language – no more than 300 words)* | | |  | | | | |
| **6f) Research Design** *(in brief lay language – no more than 300 words)* | | |  | | | | |

**Section C: Basis for Exemption**

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| 1. ***RESEARCH PARTICIPANTS: RISK, HARM, SELECTION AND CONSENT*** | | | |
| **7a) Is this research likely to involve any foreseeable risk to participants, above the level experienced in everyday life? *Yes or No?*** | | **Yes** | **No** |
|  |  |
| **7b) Does this research involve the following:** *you are advised to read the HREC Guidelines documents – see HREC Policies & Guidelines (select Yes or No):*[*http://www.ucd.ie/researchethics/information\_for\_researchers/policies\_guidelines/*](http://www.ucd.ie/researchethics/information_for_researchers/policies_guidelines/)*]* | | | |
| i | Any vulnerable groups? *(includes physical impairment, mental health impairment, capacity to consent, UCD Students and marginalized sections of society)* |  |  |
| ii | Sensitive topics that may make participants feel uncomfortable?*(i.e. sexual behavior, illegal activities, racial biases, etc.,)* |  |  |
| iii | Use of drugs? |  |  |
| iv | Invasive procedures? *(e.g. blood sampling)* |  |  |
| v | Physical stress/distress, discomfort? |  |  |
| vi | Psychological/mental stress/distress? |  |  |
| vii | Deception of/or withholding information from subjects? |  |  |
| viii | Access to data by individuals or organizations other than the investigators? |  |  |
| ix | Conflict of interest issues? |  |  |
| x | Any other ethical dilemma? *(if the answer is* ***YES*** *please provide details below)* |  |  |
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| 1. ***ETHICAL APPROVAL FROM ANOTHER BODY*** | | | | | |
| **8a) Has this study received Ethical Approval elsewhere?** *(e.g. NREC, hospital REC or other external body or for data collected by another organization for a specific purpose –Yes or No?)* | | | | **Yes** | **No** |
|  |  |
| ***If your answer is No please proceed to Section 9*** | | | | | |
| **8b) Ethical Approval from body other than UCD for this study or parts of this** *study (select Yes or No)* | | | | **Yes** | **No** |
|  |  |
| i **Name of Organization that has approved the study?** |  | **Approval No/Ref** | **Approval Date** | | |
|  |  | | |
| i Have all aspects of the study received ethical approval from an approved body? | | | |  |  |
| ii Does the approving body have jurisdiction over aspects of the study? | | | |  |  |
| Have all aspects of the study received ethical approval from an approved body?  Does the approving body have jurisdiction over aspects of the study? | | | |  |  |
| *Please note that a grant of exemption from full ethical review will only be granted by UCD HREC for those aspects of the study that have been approved and are under the jurisdiction of the approving body* | | | | | |

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| 1. ***USE OF EXISTING DATA*** |
| **If you are using existing data, please explain why this study is exempt from a full ethical review?** *( e.g. data collected by another organization for a specific purpose )* |
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**Section D: Confidentiality and Data Protection**

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| 1. ***DATA COLLECTION:*** *Do you intend to use any of the following recording devices as a means of collecting information for this research study?* | | | | **Yes** | **No** |
| 1. Audio/Sound recorder (tape/CDs/phone) | | | |  |  |
| 1. Photography (incl. digital cameras/phones) | | | |  |  |
| 1. Film/Video/DVD recorder | | | |  |  |
| 1. Computer (laptop/tablet/IPad) | | | |  |  |
| 1. Other | | | |  |  |
| ***If yes*** *is indicated for any of these devices, please indicate the specific permission that will be obtained as part of the informed consent document.* | | | | | | |
|  | | | | | | |
| ***10. DATA FORMAT:*** *Please indicate the form in which the data will be collected/stored/accessed and provide brief details: For explanation of the terms below please refer to* [*Personal Data Definitions & Examples*](http://www.ucd.ie/t4cms/Personal%20Data%20Definitions%20&%20Examples.pdf) *short guide* | | **When Collected** | | **When Stored and/or accessed** | | |
| **Yes** | **No** | **Yes** | **No** |
| **a)** | Anonymous |  |  |  |  |
| **b)** | De-identified (or anonymised) |  |  |  |  |
| **c)** | Identifiable |  |  |  |  |
| **d)** | Potentially identifiable |  |  |  |  |
| **e)** | Please provide any additional details about the data format |  | | | | |

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| ***11. PROTECTING CONFIDENTIALITY:*** *Describe* ***in detail*** *the measures that will be taken to protect the confidentiality of the data which will be collected:* | |
| 1. Who will have control of the data generated by the research for this study? |  |
| 1. Where will the data be stored/ or archived? |  |
| 1. Does your data storage/archiving comply with the HREC Guidelines? |  |
| 1. In what format will the data be stored/archived? |  |
| 1. How long will the data be stored/archived?  *Please explain if the data is to be stored for this study only or made available for future research/researchers.* |  |

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| 1. ***DATA COLLECTION RESPONSIBILITY:*** | | | | |
| 1. Who will be responsible, for the secure storage/archiving of, and for, control of access to the data generated by the research, until it has been either archived or destroyed?   Provide a name of a UCD staff member or UCD school or external organisation in this answer |  | | | |
| 1. Who will be responsible for archiving or destroying the data at the end of the period indicated in answer to   Q 19e)? Provide a name of a UCD staff member or UCD school or external organisation in this answer |  | | | |
| 1. Please confirm what will happen to the data collected at the end of the study? | | **Archived** | **Destroyed** | **Other** |
|  |  |  |

**Section E: Signed Declaration**

**PLEASE NOTE:** By submitting this form, the applicant and supervisor (if applicable), are agreeing to the terms and conditions and declaration below.

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| --- | --- |
| ***GUIDELINES: please confirm that you have read the following*** *(select Yes or No)****:*** | **Yes** |
| 1. *HREC Guidelines and Policies specifically Relating to Research Involving Human Subjects:* <http://www.ucd.ie/researchethics/policies_guidelines/> |  |
| 1. *The UCD Data Protection Policy:* <http://www.ucd.ie/dataprotection/policy.htm> |  |
| 1. *The SIRC Office Insurance Guidelines for Researchers* <https://www.ucd.ie/sirc/insurance/humanresearchinsurance/>  *and associated* ***mandator****y self-assessment insurance checklist* |  |
| 1. *The General Data Protection Regulation:* [*https://www.dataprotection.ie/docs/GDPR/1623.htm*](https://www.dataprotection.ie/docs/GDPR/1623.htm) |  |
| 1. *The Data Protection Guidelines on Research in the health sector, (if applicable):*   <https://www.dataprotection.ie/documents/guidance/Health_research.pdf> |  |
| 1. *The Health Research Regulations:* [*http://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/health-research-regulations-2018/*](http://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/health-research-regulations-2018/) |  |
| 1. *The Human Research Ethics Risk Assessment (if applicable) for face-to-face interactions with research subjects:* <https://www.ucd.ie/sirc/coronavirus/returntocampusworking/> |  |
| 1. *The UCD GDPR Policies & Procedures:* <http://www.ucd.ie/gdpr/policiesprocedures/> |  |

**For the UCD REC and HREC Policies and Guidelines please see:** <http://www.ucd.ie/researchethics/policies_guidelines/>

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| **I, the researcher, have read the** *HREC Guidelines and Policies specifically Relating to Research Involving Human Subjects* **and agree to abide by them in conducting this research. I confirm that the information provided on this form is correct and accurate**.  ***We the undersigned researchers acknowledge or agree with the University:***   1. *It is our sole responsibility and obligation to comply with all domestic Irish and European legislation and to obtain such statutory consents as may be necessary;* 2. *Not to commence any research until any such consents have been obtained;* 3. *To furnish to the proper officer of UCD a true copy of any consent obtained;* 4. *That neither the University, the Committee, nor individual members of the Committee accept any legal obligation (to us or to any third party) in relation to the processing of this application or to any advice offered in respect of it nor for the subsequent supervision of the research;* 5. *That the research will be conducted in accordance with any approval granted by the Committee and in conformity with the documentation submitted with this application and with licence granted under any legislation;* 6. *That the undersigned researcher(s) have read the most recent UCD Research Ethics Committee Guidelines and Policy for Ethical Approval of Research involving Humans –* *which are available on the UCD website (*[*www.ucd.ie/researchethics*](http://www.ucd.ie/researchethics)*) and agree to abide by them in conducting this research;* 7. *Confirm that the information provided on this form is correct and accurate;* 8. *In conducting research, a researcher has both ethical duties and legal obligations. Compliance with one set of responsibilities does not guarantee compliance with the other - what is legally permissible may not be ethical and vice versa.* ***It is for the researcher to inform himself and herself as to what ethical duties and legal obligations apply to his or her research and to comply with these duties and obligations – this includes being informed about General Data Protection Guidelines (GDPR);*** 9. *It is not acceptable for an applicant to treat the grant of ethical approval as absolving them from the responsibility of informing themselves of their legal responsibilities in relation to data protection and of complying with these;* 10. *It must be understood that any ethical approval granted is premised on the assumption that the research will be carried out within the limits of the law;* 11. *Ethical approval does not constitute any sort of advice or representation to the applicant that compliance with the requirements, as laid down by the UCD Human Research Ethics Committee, will be sufficient to comply with the applicable law in the area.* |
| |  | | --- | | **I apply for Approval for Exemption from Full Review in regard the research protocol summarised above.**  Copies of all supporting documentation relating to this research study have been submitted to the Supervisor  Signature of Applicant: Date: | | **I have read the above application, and am satisfied that the study appears to meet all requirements for a Grant of Ethical Approval with Exemption from Full Review from UCD HREC.**  All appropriate supporting documentation relating to this research study has been approved  Signature of Supervisor: Date:  **[Full names added above or scanned signature will count as confirmation of details.]** | |

1. Where the target population comprises students drawn from two or more schools and the survey encompasses university-wide activities or services [↑](#footnote-ref-1)