##### Description: Description: ucd_brandmark_colour[1]

##### Undergraduate & Taught Masters Research Ethics Committee

#####  – UCD School of Medicine

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##### Human Subjects Ethical Review Application Form

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| ***Note: INSURANCE –* The UTMREC-SM is not 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 incumbent on every applicant to ensure that the appropriate insurance cover is in place for their research. This can be done via the use of the mandatory self-assessment checklist which can be found at the link above.  |

**Section A: General Information**

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| 1. ***SUBMISSION FOR FULL ETHICAL REVIEW***
 | **Yes** | **No** |
| **1a)** Has this proposal been submitted to any other research ethics committee? ***If yes***, please provide details below of which committee and the outcome. | [ ]  | [ ]  |
|  |
| **1b)** Is this a pilot study? | [ ]  | [ ]  |
| **1c)** Have you attended a Research Ethics Application Advisory Consultation?  | [ ]  | [ ]  |
| **1d)** Are you seeking permission to access UCD Students from more than one school? | [ ]  | [ ]  |
| **1e)** 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 will be sought (by the Office of Research Ethics) from the University Student Survey Board (USSB) after the ethical review and approval has been granted).* | [ ]  | [ ]  |
| **1f)** Do you or other investigators require a Garda Vetting Certificate for the purpose of this study? *(If* ***YES****, please confirm your compliance in Section C, Q12)* | [ ]  | [ ]  |
| **1g)** Does your study involve face-to-face interactions with participants? *If yes, then please complete the Human Research Ethics Risk Assessment and follow the instructions in the template:* [*https://www.ucd.ie/sirc/coronavirus/returntocampusworking/*](https://www.ucd.ie/sirc/coronavirus/returntocampusworking/) | [ ]  | [ ]  |

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| 1. ***PROJECT DETAILS***
 |
| **2a) Project Title** *In lay terms and short – 15 words max* |  |
| **2b)** | Proposed Study Start Date:(dd/mm/yy) | Proposed Study Completion Date:(dd/mm/yy) | Proposed Start Date of Data Collection for this submission:(dd/mm/yy) | Proposed Completion Date of Data Collection for this submission:(dd/mm/yy) |
|  |  |  |  |

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| 1. ***APPLICANT / PRINCIPAL INVESTIGATOR DETAILS*** *If answers are not clear the form will be returned*
 |
| **3a) Name of student (applicant)** |  |
| **3b) Applicant’s UCD Email Address:** |  |
| **3c) Applicant’s UCD Student Number:** |  |
| ***Note:*** *UCD Staff members are Principal Investigators (PI); UCD Students are applicants and must provide supervisor’s name below* |
| **3c) Programme / level of study in UCD School of Medicine** *(please select the relevant option):* | **Undergraduate** | **Taught Post-Graduate** |
| **Medicine** | **Radiography** | **BHLS** | **Physiology** | [ ]  |
| [ ]  | [ ]  | [ ]  | [ ]  |
| **3d) Is research part of SSRA programme?***(Provide project number, if relevant)* | **Yes** | **No** | **Project Number** |
| **[ ]**  | **[ ]**  |  |
| **3e) If taught programme, please provide name of course**  |  |
| **3f)** **Supervisor’s Name** *(including title e.g. Prof., Dr. other etc.,)* |  | **UCD / external Telephone:** | **UCD / external organisation Email:** |
| **3g) Has your supervisor reviewed this submission?**  | **Yes** | **No.** *Why Not?* |
| **[ ]**  | **[ ]**  |

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| 1. ***INTERNAL / EXTERNAL INVESTIGATOR(S) / ORG DETAILS*** *(if applicable) name all investigators on project*
 |
| **4a)** **UCD Principal Investigator(s)** & affiliations  |  |
| **4b)** **External Investigator(s)** Names |  |
| **4c)** **Name & Address of external Organization** *if applicable* |  |
| **4d)** **Details of relationship** between the UCD investigators, the external investigators and the project |  |
| **4e)** **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** |
| **[ ]**  | **[ ]**  |
| **4f)** Describe briefly the Data Sharing and Data Management Agreement |  |

**Section B: Research Design & Methodology**

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| 1. ***5. RESEARCH PROPOSAL***
 |
| **5a) Has this topic been studied before? *If yes,*** why is an additional study needed? |  |
| **5b) Provide a brief description of research** | *The description must be presented in everyday or lay language and not more than 250 words each* |
| i | the aims and objectives of the study |
|  |
| ii | the scientific/theoretical background of study |
|  |
| **5c) Research design**  | *Describe in not more than 250 words each* |
|  |
| i | the methods of data collection |
|  |
|  ii | the size and composition of sample |
|  |
| iii | how the size of the sample was determined |
|  |
| vi | Will there be a pilot study run initially?  |
|  |
| v | the methods of analysis to be used |
|  |
| vi | Will formal statistical procedures be used? |
|  |
| **5d) Expertise available to the researcher(s) for analysis of the data** | *Describe in not more than 250 words each* |
|  |
| **5e) Methods of data collection** *please indicate Yes or No* | Yes/No? | *Describe briefly* |
| 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)* |  |  |

**Section C: Ethical Issues and Dilemmas**

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| ***6. ETHICAL DILEMMAS & ISSUES:*** *Please identify all ethical dilemmas and issues which may arise in the course of the study and provide details of how you propose to address them.* |
|  |
| If you have not identified any ethical issues or dilemmas please complete and submit a Low Risk Projects Form by email to Medicinerec@ucd.ie  |

**Section D: Research Participants: Risk, Harm, Selection and Consent**

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| ***7. SELECTION AND RECRUITMENT OF PARTICIPANTS*** |
| **7a) Who are the participants?** *(including size and composition)* |  |
| **7b) Where are you recruiting the participants from and how will they be selected?**  |  |
| I | Do you have permission to access these participants? *Provide details of organization/group and attach 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* |
| ii | Please state clearly who will approach potential participants? |  |
| **7c)** **How will the research participants in this study be screened, please give details of your screening criteria for recruitment/selection of participants** |  |
| i | Inclusion criteria. What inclusion criteria operate? |  |
| Ii | Exclusion criteria. What exclusion criteria operate? |  |

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| ***8. VULNERABLE PARTICIPANTS*** *If the participants (or controls) belong to any of the following vulnerable groups below please give details (includes physical impairment, mental health impairment, capacity to consent, UCD Students and marginalized sections of society)* |
| a) | Children under 18 years of age |  |
| b) | University Students *(see policies – accessing students and recommendations on using students in research)* |  |
| c) | People who have language difficulty |  |
| d) | People who have a recognised or diagnosed intellectual, physical or mental impairment |  |
| e) | Older people *(in relation to physical impairment, mental health impairment, capacity to consent)* |  |
| f) | People confined to institutions *(prisoners, residents in 24 hour nursing facilities)* |  |
| g) | Persons in unequal relationships with the researcher *(teacher/student; therapist/client; employer/employee)* |  |
| h) | Marginalized sections of society |  |
| i) | Others *(please specify)* |  |
| ***9. PROTECTING VULNERABLE PARTICIPANTS:*** *If the study participants (or controls) belong to any of the vulnerable groups please state what special arrangements will be made to protect them (including Garda Vetting requirement) and to deal with issues of consent/assent.* |
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| ***10. RISKS TO PARTICIPANTS:***  | **Yes or No?** | **Please indicate the level of risk for research participants, and provide brief details:** |
| **a)** Extreme risk? |  |  |
| **b)** High Risk? |  |  |
| **c)** Some Risk? |  |  |
| **d)** Minimal Risk*?* |  |  |
| **e)** Please indicate the steps that will be taken to control this risk or to address any harm associated with participant *(e.g. debriefing procedures etc.,)* |
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| ***11. INFORMATION LEAFLET CHECKLIST:*** *Please confirm that the following issues have been addressed in your Information leaflet for participants Please note that the items listed below are also the headings to be used in your information sheet and are to be addressed to the participant* | **Yes** | **No** |
| 1. Introductory statement:
* Researcher’s name and descriptor (Professor, Dr. Mr. Ms, other)
* Name of researcher’s School
* The topic and title of the research.
 | **[ ]**  | **[ ]**  |
| 1. ‘What is this research about?’
 | **[ ]**  | **[ ]**  |
| 1. ‘Why I am doing this research?’
 | **[ ]**  | **[ ]**  |
| 1. ‘Why have you been invited to take part?’
 | **[ ]**  | **[ ]**  |
| 1. ‘How will your data be used?’
 | **[ ]**  | **[ ]**  |
| 1. ‘What will happen if you decide to take part in this research study?’
 | **[ ]**  | **[ ]**  |
| 1. ‘How will your privacy be protected?’
 | **[ ]**  | **[ ]**  |
| 1. ‘What are the benefits of taking part in this research study?’
 | **[ ]**  | **[ ]**  |
| 1. ‘What are the risks of taking part in this research study?’
 | **[ ]**  | **[ ]**  |
| 1. ‘Can you change your mind at any stage and withdraw from the study?’
 | **[ ]**  | **[ ]**  |
| 1. ‘How will you find out what happens with this project?’
 | **[ ]**  | **[ ]**  |
| 1. Contact details for further information

*Please be aware of the risks in providing your personal phone details and the implications this might have when dealing with participants under 18* | **[ ]**  | **[ ]**  |
| *If the above headings* ***are not*** included in your information leaflet, please explain and justify why below |
|  |

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| ***12. CONSENT PROCEDURES:*** *Describe the procedures by which consent will be obtained* | **Yes** | **No** |
| 1. **Is written consent to be obtained?**
 | **[ ]**  | **[ ]**  |
| i | **If yes,** describe the procedures by which written consent will be obtained |  |
| ii | **If no,** describe procedures regarding how consent will be obtained  |  |

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| ***13.* *EXPENSES & REIMBURSEMENTS*** *(Please read* [*REC Guidelines on Expenses & Incentives*](http://www.ucd.ie/researchethics/t4media/HREC%20Guideline%20on%20Expenses%20and%20Incentives%20220218.pdf) *before completing this section)* | **Yes** | **No** |
| 1. **Will payment of any kind, including expenses, be made to participants?**
 | **[ ]**  | **[ ]**  |
| i | **If yes,** please provide details and justification below. |
|  |

**Section E: Confidentiality and Data Protection**

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| ***14. PROTECTION PARTICIPANT IDENTITY:*** *What arrangements are in place to ensure that the identity of each participant remains confidential?* |
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| ***15. 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/mobile phone)
 | **[ ]**  | **[ ]**  |
| 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.*  |
|  |
| ***16. DATA FORMAT:*** *Please indicate the form in which the data will be collected/stored/accessed (bearing in mind you may be creating a data base) 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%26%20Examples.pdf) *HG3B short guide* | **Collected** | **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 *Please Note – consent forms; recordings; transcripts; databases, may need to be handled separately – please provide details, if applicable* |  |
| *Submissions which propose face-to-face interactions between participants and researchers (e.g. focus groups, interviews, physical tests are not anonymous or de-identified at the collection stage –* ***please answer correctly*** |

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| ***17. PROTECTING CONFIDENTIALITY:*** *Describe* ***in detail*** *the measures that will be taken to protect the confidentiality of the data/database 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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| ***18.DATA COLLECTION AND DATA/DATABASE MANAGEMENT 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** |
| **[ ]** **Go to Q19** | **[ ]** **Go to Q20** | **[ ]** **Go to Q21** |

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| **19. *ARCHIVING DATA/DATABASE:*** *please indicate what will happen to the data?* |
| 1. **Who** in UCD will be responsible for the archive and future use of the data? *Provide a name of a UCD staff member or UCD school or external organization in this answer*
 |  |
| 1. Also give details of whether it will be **intended for personal use** only? [[2]](#footnote-2)
 |  |
| 1. Will the archived data be **made available to other researchers?** If yes, then how?
 |  |
| 1. Please provide details about how and where the data is to be archived and

details on the future use of the data – who will be allowed to access the data, what restrictions will be in put in place and any other criteria for accessing this data in the future by a third party? |  |

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| 1. ***DESTROYING DATA/DATABASE:*** *please explain why you are destroying the data?*
 |
| 1. Please justify **why** the data will be destroyed
 |  |
| 1. Confirm **who** will be responsible for the destruction? Provide a name of a UCD staff member or UCD school or external organization in this answer
 |  |
| 1. When will the data/database be destroyed?
 |  |

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| 1. ***DATA/ DATABASE MANAGEMENT:*** *Please explain what will happen to the data if not being destroyed or archived?*
 |
|  |
| **22. *FUTURE USE OF DATA/DATABASE:*** *Please confirm if the data you collected for this study is intended to be used by you or other researchers for further research or publication at a later date*  |
|  |

**Section F: DECLARATION**

|  |  |
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| ***GUIDELINES: please confirm that you have read the following:*** | **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 UCD GDPR Policies & Procedures:* <http://www.ucd.ie/gdpr/policiesprocedures/>
 | [ ]  |
| 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 SIRC Office Insurance Guidelines for Researchers* <https://www.ucd.ie/sirc/insurance/humanresearchinsurance/>  *and associated* ***mandator****y self-assessment insurance checklist*
 | [ ]  |

**For all the latest versions of the UCD REC and HREC Policies and Guidelines please see the research ethics website:** <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:****a) 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;**b) Not to commence any research until any such consents have been obtained;**c) To furnish to the proper officer of UCD a true copy of any consent obtained;**d) 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;**e) 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;**f) 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;**g) Confirm that the information provided on this form is correct and accurate;**h) 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);****i) 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;* *j) 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;* *k) 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.****l) FINAL SIGN-OFF IS REQUIRED POST-REVIEW AND FOLLOWING SATISFACTORY RESPONSES TO ANY CLARIFICATIONS.*** Before the final Approval Letter is issued by the UTMREC-SM, the Applicant and Supervisor must sign off on the declaration above. Please sign below and **save in Word format** before submitting final version to medicinerec@ucd.ie.  |

|  |  |  |
| --- | --- | --- |
| **Signature of Applicant / Researcher** |  | **Date** |
| **Signature of Supervisor / PI** |  | **Date** |

**Further information from:** [www.ucd.ie/researchethics](http://www.ucd.ie/researchethics) **or** email: medicinerec@ucd.ie

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)
2. Please note that in the context of health research of any kind, specific consent must be obtained from a research subject for the sharing of his or her data with persons other than the researchers, the nature of the research of which this sharing of data may form part must be adequately specified for the subject at the point that consent is obtained and approval for such sharing of data must be obtained from the relevant ethics committee. [↑](#footnote-ref-2)