##### Description: Description: ucd_brandmark_colour[1] **Human Subjects Research Ethics Application Form**

| **The purpose of this document is to highlight common errors made and to guide you****in the completion of each section.****The main advice to you is:** **(i) READ THE QUESTION CAREFULLY** **(ii) DO NOT PROVIDE INFORMATION BEYOND THE SCOPE OF THE QUESTION****(III) KEEP YOUR ANSWERS SUCCINCT** **(iv) AVOID REPETITION & REPEATED TYPOS****(v) DO NOT LEAVE QUESTIONS BLANK – ANSWER ALL QUESTIONS EVEN IF SAYING ‘N/A’ (not applicable)****Tip:*** **Double Click the Tick boxes and select ‘Checked’ rather than trying to add a tick mark or an ‘X’ nearby**
 |
| --- |

| ***Note: INSURANCE –* The HREC is not responsible for overseeing insurance requirements.** *Applicants should refer to* [*UCD SIRC Office*](https://www.ucd.ie/sirc/insurance)  *for information on insurance for human research. Every applicant must ensure that the appropriate insurance cover is in place for their research.* |
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**PLEASE NOTE THAT THIS FORM SHOULD NOT EXCEED 25 PAGES MAX – long application forms will be returned**

**Section A: General Information**

| 1. ***SUBMISSION FOR FULL ETHICAL REVIEW***
 | **Yes** | **No** |
| --- | --- | --- |
| **1a) Is this study for a full ethics review by one of the HRECs?**  | ☐ | ☐ |
| **1b)** **Has this proposal been submitted to any other research ethics committee?** *If yes, please provide details below of which committee and the outcome.* *Double click the box and choose ‘checked’ for either yes or no (not both)* | ☐ | ☐ |
|  |
| **1c)** **Is this a pilot study?** | ☐ | ☐ |
| **1d) Access to Students:** *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-0)* ***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* |
| **Yes** | **No** | **Yes** | **No** | **Yes** | **No** |
| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| **1e)** 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) NOTE: You must provide a copy in your supporting documents* | **Yes** | **No** |
| ☐ | ☐ |
| **1f)** Does your study require a **Data Protection Impact Assessment**? If yes, or you do not know, please contact the DPO/GDPR for further information and guidance on how to complete a DPIA. See “[Managing Risk in Personal Data Processing](https://www.ucd.ie/gdpr/guidanceresources/)” do not provide the DPIA as part of your submission unless you are requested to do so after the review. |  ☐ |  ☐  |

| 1. ***PROJECT DETAILS***
 |
| --- |
| **2a) Project Title** *Please provide a title that indicates the subject of the study and avoid abstract titles or jargon.* | *In lay terms and short –* ***15 words max*****Common Mistakes Include:****• Title is too scientific/technical or has too many anacronyms or abbreviations****• Title is not succinct and does not convey what the study is about****• Title does not align with Information Sheet Title** |
| **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)***This date must post-date the ethics review date by at least two months* | **Proposed Completion Date of Data Collection** **for this submission:****(dd/mm/yy)** |
|  |  |  |  |
| **Common Mistakes Include:****• Start date for data collection too close to HREC review date and leaving insufficient time for completion – please allow at least two months post-initial review date to accommodate your review response(s), sign-offs, or possible resubmission to the following monthly review.** |

| 1. ***APPLICANT / PRINCIPAL INVESTIGATOR DETAILS*** *If answers are not clear the form will be returned*
 |
| --- |
| **3a) Name of Applicant/ Principal Investigator (PI)** *include title* | **Common Mistakes:*** **Name of applicant does not match the name of the applicant that submitted via Infohub. The applicant must be the person who is submitting via Infohub as the person responsible for the study and the review sign-off.**
 |
| ***Note: UCD Staff members are Principal Investigators (PI); UCD Students are applicants and must provide supervisor’s name***  |
| **3b) Applicant’s position in UCD** *(please select the relevant option):* | **Academic** | **Postgraduate** | **Other** |
| *Staff*  | *Post Doc* | *PhD* | *Taught Masters**(MSc , Diploma)* |  |
|  |  |  |  |
| **3c) Applicant’s Academic / Professional Qualifications** |  |
| **3d) Applicant’s Contact details**  | **Name of Applicant’s School** | **Email Address** *(applicant’s name NOT Student Number)* |
| **Common Mistake:*** **Not correctly naming your school or admin unit**
 | **Common Mistake:*** **Not providing a UCD email**
 |
| **3e) Applicant’s most recent relevant publications, if any** | *(please limit to short list of* ***no more than five*** *publications)* |
| **3f) Indicate if this study is for an academic qualification**  | *PhD ?* | *Taught Masters/MSc/Diploma?* | *Other? Give details* |
|  |  |  |
| **3g)** **Supervisor’s Name** *(including title e.g. Prof., Dr. other etc.,)* |  | UCD Telephone: | UCD Email: |
| **3h)** *If yes,* **Has your supervisor reviewed this submission?**  | *Yes* | *No. Why Not?* |
|  |  |
| *Students note: your supervisor must provide an endorsement letter – please include with support docs accompanying this form*. |
| **3i) Funding** *if applicable* | **Source** *(details of funding programme)* | **Amount** |
|  |  |
| *If funded commercially, are there any restrictions on the freedom**of the researcher to publish the results? Please specify:* |  |

| 1. ***INTERNAL / EXTERNAL INVESTIGATOR(S) / ORG DETAILS*** *(if applicable) name all investigators on project*
 |
| --- |
| **4a)** **UCD 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**If yes, describe briefly in the box below* | **Yes** | **No** |
| **☐** | **☐** |
| **Common Mistakes Include:*** **Not being brief enough**
* **Ticking ‘yes’ but stating here that it will be in place rather than it is in place**
* **Not stating clearly that the external investigator will have access to the data**
 |
| **4f**) 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**

| **Common Mistakes Include:*** **Not being brief enough**
* **Not answering Q5c) and Q5e) fully**
 |
| --- |

| 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 |
|  |
| iv | Will there be a pilot study run initially?  |
|  |
| v | the methods of analysis to be used |
|  |
| vi | Will formal statistical procedures will 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 *(incl. secondary data)*  |  |  |
| ix | surveys/questionnaires  |  |  |
| x | audio/video recordings  |  |  |
| xi | other *(please specify)* |  |  |

**Section C: Ethical Issues and Dilemmas**

| ***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.* |
| --- |
| **Common Mistakes Include:*** **Making broad statements about ethical best practice that has no direct link to your study**
* **Confusing ethical dilemmas with the known risks and harms of the study**
* **Not anticipating the areas where your study might become problematic for participants and/or the researchers**
* **Listing potentially unexpected consequences of your data collection but not providing any detail as to how you will handle the situation or what mechanisms you will put in place to minimise**
 |
| If you have not identified any ethical issues or dilemmas please complete and submit a Low Risk Study Review Form by email to research.ethics@ucd.ie  |

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

| ***7. SELECTION AND RECRUITMENT OF PARTICIPANTS*** |
| --- |
| **7a) Who are the participants?** *(including size and composition)* | Common Mistake:* Not stating specifically who the participants are
 |
| **7b) Where are you recruiting the participants from and how will they be selected?**  | Common Mistake:* Not stating clearly how you will access the participants
 |
| I | Do you have permission to access these participants? *Provide details of organization/group and attached a copy of the permission if applicable* | Common Mistake:* Confusing permission to access participants with consent
* Not stating who (or what org) specifically is providing permission to access
 |
| *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? |  |

| ***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*](https://www.ucd.ie/registry/prospectivestudents/admissions/policiesandgeneralregulations/vettingrequirements/) *requirement) and to deal with issues of consent/assent.* |
| **Common Mistakes include:*** **Answers do not align with the Information Sheet and Consent/Assent Forms**
 |

| ***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*?* |  | **Common Mistake:*** **Stating that there is no risk yet seeking a full review – if there is no risk then a low risk review would be more appropriate**
 |
| **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.,)* |
|  |

| ***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 benefits to the researcher if you take part in this 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 |
| **Common Mistakes Include:*** **Ticking ‘Yes’ but not using the Headings in this question in the Information Sheet**
* **Not explaining why a heading is not included in your information sheet**
 |

| ***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  |  |

| ***13.* *EXPENSES & REIMBURSEMENTS*** *(Please read* [*REC Guidelines on Expenses & Incentives*](https://www.ucd.ie/researchethics/t4media/HG2C%20Expenses%20and%20Incentives.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**

| ***14. Data Format at******point of COLLECTION*** Please list in the box below each and every type of data that will be collected (e.g. audio recordings, video, transcripts, surveys, physiological measures, and include consent forms) and for each, specify whether it is classed as ***Anonymous***, ***Potentially Identifiable***, or ***Identifiable*** at point of collection |
| --- |
| **Common Mistakes Include:*** **Either providing a full listing here but not reflecting that list in the consent form (item for item) or listing all in the consent form but not in this answer**
 |

| ***15. Data Format when STORED*** For all data types in the above box designated as potentially identifiable or identifiable, specify in each case how data protection and confidentiality will be maximised. Will it be ***pseudonymised*** (reversibly de-identified, with key linking codes to names retained), or ***anonymised*** (irreversibly de-identified, where no key exists)? |
| --- |
|  |

| ***16. 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.*
 |  |

| ***17. DATA COLLECTION AND DATA/DATABASE MANAGEMENT RESPONSIBILITY:*** |
| --- |
| 1. Who will be responsible, for the secure storage/archiving of, or/control of access to the data generated by the research, until it has been either stored, archived or destroyed?

*Provide a name of a UCD staff member and 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 17a)? *provide a name of a UCD staff member and 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 Q18** | **☐****Go to Q19** | **☐****Go to Q20** |
| ***NOTE ON DATA PROTECTION IMPACT ASSESSMENTS (DPIAs)*** *A study may require a DPIA and* ***it is the researcher’s responsibility to find out if they need one.*** *Please see the* [*UCD GDPR Website*](https://drive.google.com/file/d/1j6APgSPThyOwa-VTSbObPj3AN8f7iU8F/view) *for a short guide. All queries should be directed to the UCD DPO* |

| **18. *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 name of a UCD staff member and UCD school or external name/ org*  |
|  |
| 1. Also give details of whether the data will be **intended for personal use** only? **[[2]](#footnote-1)**
 |  |
| 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?* |
|  |

| 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 and UCD school or external organisation in this answer*
 |  |
| 1. When will the data/database be destroyed?
 |  |

| 1. ***DATA/ DATABASE MANAGEMENT:*** *Please explain what will happen to the data if not being destroyed or archived?*
 |
| --- |
|  |
| **21. *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**

| ***GUIDELINES: please confirm that you have read the following*** *(select* ***yes*** *to the relevant guidelines for your study)* | **Yes** |
| --- | --- |
| 1) [*HREC Guidelines and Policies*](https://www.ucd.ie/researchethics/policiesguidelines/hrecguidelines/) *specifically Relating to Research Involving Human Subjects* | ☐ |
| *2) The UCD* [*Data Management Policy*](https://hub.ucd.ie/usis/%21W_HU_MENU.P_PUBLISH?p_tag=GD-DOCLAND&ID=227) | ☐ |
| *3) The UCD* [*GDPR Policies & Procedures*](http://www.ucd.ie/gdpr/policiesprocedures/)and [Data Protection Impact Assessments](https://www.ucd.ie/gdpr/guidanceresources/) (DPIAs) | ☐ |
| *4) The* [*General Data Protection Regulation*](https://www.dataprotection.ie/docs/GDPR/1623.htm) | ☐ |
| 5) [*The Health Research Regulations*](http://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/health-research-regulations-2018/)*:*  | ☐ |
| *6) The* [*SIRC Office Insurance Guidelines for Researchers*](https://www.ucd.ie/sirc/insurance) *and associated* ***mandator****y self-assessment insurance checklist* | ☐ |

**Please note for all** [**UCD REC and HREC Policies and Guidelines**](https://www.ucd.ie/researchethics/policiesguidelines/)

| **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 researchers acknowledge and 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 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 be informed 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) and UCD Insurance Requirements;***
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*
12. ***FINAL SIGN-OFF IS REQUIRED POST-REVIEW AND FOLLOWING SATISFACTORY RESPONSES TO ANY CLARIFICATIONS.*** Before the final Approval Letter is issued, the Applicant and Supervisor/Head of School will be instructed via InfoHub/SISWeb to provide a sign off on the declaration above.
 |
| --- |

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

**PLEASE NOTE THAT THIS FORM SHOULD NOT EXCEED 25 PAGES MAX – long application forms will be returned**

1. Where the target population comprises students drawn from two or more schools and the survey encompasses university-wide activities or services [↑](#footnote-ref-0)
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-1)