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

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

***N.B. Please do not alter the format of this form and submit it as a Word document only***

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| ***NOTE ON SUBMITTING This form should be submitted by the student that is completing the project but must be approved and signed by a member of staff (PI, Module coordinator, or Programme Director.*** *Please see website for details* [*https://www.ucd.ie/medicine/research/researchethics/howtoapply/*](https://www.ucd.ie/medicine/research/researchethics/howtoapply/)  |

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| ***NOTE ON INSURANCE The UTMREC-SM is no longer responsible for overseeing insurance requirements.*** *Applicants should refer to* <https://www.ucd.ie/sirc/insurance>  *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.* |

**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 this low risk study form for the study summarised below, on the basis that*** this research protocol is **low risk** and meets one or more of the low risk criteria 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 complete section A, provide brief details of the project / existing approval in Section C Question 8 below, and provide a pdf copy of that approval. Other sections need not be completed.*
 |  |  |
| 1. Study involves clinical audit or retrospective chart review and has hospital permission / approval). **If yes,** *Please provide a pdf copy of that permission / approval and use Section C Question 8 / 9 to explain*.
 |  |  |
| 1. the study has been reviewed and approved by a recognised REC but is using participants from UCD.

**If yes,** *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 and 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
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| 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*

***Please note that all submissions for low-risk studies that involve accessing UCD students require a Chair’s Review*** |
| **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* |
| **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)** |
|  |  |  |  |
| **3c) At what location will research be conducted?***(and where will data be held, if different?)* |  |

*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 / PRINCIPAL INVESTIGATOR DETAILS Mandatory*** *– all question* ***must*** *be completed fully or enter n/a where appropriate*
 |
| **4a) Name of student (applicant)** |  |
| **4b) Applicant’s UCD Email Address:** |  |
| **4c) Applicant’s UCD Student Number:** |  |
| ***Note:*** *UCD Staff members are Principal Investigators (PI); UCD Students are applicants and must provide supervisor’s name below* |
| **4d) Programme / level of study in UCD School of Medicine** *(please select the relevant option):* | **Undergraduate** | **Taught Post-Graduate** |
| **Medicine** | **Radiography** | **BHLS** | **Physiology** | [ ]  |
| [ ]  | [ ]  | [ ]  | [ ]  |
| **4e) Is research part of SSRA programme?***(Provide project number, if relevant)* | **Yes** | **No** | **Project Number** |
| **[ ]**  | **[ ]**  |  |
| **4f) If taught programme, please provide name of course**  |  |
| **4g) UCD Module / Programme Coordinator** *(please also provide UCD email address)* |  |
| **4g) 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 / external Telephone:** | **UCD / external organisation Email:** |
| **5b) UCD Investigator(s) and affiliations** | *(name all investigators on project)* |
|  |
| **5c) External Investigator(s) Name** *if applicable* |  | **Relationship with External Organization:**  |  |
| **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 to you*
 |
| **6a) Methods of data collection** | ***Yes*** | ***No*** | *(please select the appropriate box and provide brief details)* |
| i | standard educational practices  |  |  |  |
| ii | standard educational tests  |  |  |  |
| iii | standard personality tests  |  |  |  |
| iv | standard psychological tests  |  |  |  |
| v | interviews or focus groups *If your study involves face-to-face interactions with participants* ***in a healthcare setting****, including UCD students, you 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.***  |  |  |  |
| 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 and how?** *Explain who will approach participants and include any advertisements to be used* |  |
| i | Do you have permission to access these participants and/or their data? *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? Indicate Yes or No** | **Written** | **Oral**  | **Audio** |
|  |  |  |
| i | Which of these documents will you be using? **Indicate Yes or No****Please provide any such documents with your application** | **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 Low Risk**

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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?** *(select 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?*(including secondary data)* |  |  |
| 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 – select 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 Organisation that has approved the study?** |  | **Approval No/Ref** | **Approval Date** |
|  |  |
| (ii) Have all aspects of the study received ethical approval from an approved body?  |  |  |
| (iii) Does the approving body have jurisdiction over aspects of the study? |  |  |
| (iv) Briefly outline the proposed project and how it relates to the approved project. |
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| *Please note that approval for a low-risk study will only be granted by UTMREC-SM 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/SECONDARY DATA***
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| **9a) If you are using existing data, please explain why this study is low-risk?** *(e.g. data collected by another organization for a specific purpose)* |
|  |
| **9b) For Health Research Only: Please state whether subjects originally consented to this intended secondary use, and if not, whether any required approval from Health Research Consent Declaration Committee (HRCDC) is being sought?** *e.g. health related data from the Central Statistics Office (CSO)* |
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**Section D: Confidentiality and Data Protection**

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| ***10. 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 |
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| ***11. 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)? |
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| ***12. 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 12e)? 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:*** | **Yes** |
| 1. *HREC Guidelines and Policies specifically Relating to Research Involving Human Subjects:* <https://www.ucd.ie/researchethics/policiesguidelines/>
 | [ ]  |
| 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:** <https://www.ucd.ie/researchethics/policiesguidelines/>

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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 (*<https://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 or 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.*
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| **Signature of Applicant / Researcher** |  | **Date** |
| **Signature of Supervisor / PI** |  | **Date** |

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)