

SCHOOL OF LINGUISTIC, SPEECH AND COMMUNICATION SCIENCES

TRINITY COLLEGE DUBLIN

**RESEARCH ETHICS APPLICATION FORM**

**PLEASE NOTE THE FOLLOWING:**

* **Incomplete applications cannot be processed** and will be returned for completion.
* Forms **without the** applicant(s) and research supervisor(s) (for student applications) confirmation of declaration/s section/s completed cannot be processed.
* Forms **without a completed checklist** (Section 1) cannot be processed.
* Applications must be **typed** and not hand-written and submitted as a single document (application & all appendices)

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| Please complete the application form and return **one electronic copy (with supervisor signature)** to:  [slscs@tcd.ie](mailto:slscs@tcd.ie) | | | | | | | | | | | Office use only: | | | |
| *REF No:* | | | |
| *Meeting date:* | | | |
| *Decision:* | | | |
| *Remarks:* | | | |
| **APPLICANT NAME:** |  | | | | | | | | | | | | | |
| **APPLICANT EMAIL:** |  | | | | | | | | *(Please use your* ***tcd.ie*** *email address)* | | | | | |
| **SLSCS STAFF MEMBER?** | Yes | | | *Job title* | | | | | | | | | | |
| **STUDENT NUMBER** |  | | | | | | | | | | | | | |
| **SLSCS STUDENT?** | UG |  | MSc | |  | MPhil |  | MLitt | |  |  | | | |
|  | PhD |  | CLCS | |  | CSLC |  | CDS | |  |  | | | |
| **SUPERVISOR NAME:** |  | | | | | | | | | | | | | |
| **PROJECT SHORT TITLE:** |  | | | | | | | | | | | | | |
| **DATE OF SUBMISSION TO REC:** | Full resubmission of a previous application? | | | | | | | | | | Yes |  | No |  |

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| **SPECIFY YOUR ROLE IN PROJECT** | | |  | | | | | |
| Single Researcher |  | | Principal Investigator | |  | Co-investigator | |  |
| Please provide the name, qualification and position of each person associated with this research project  (add further rows as required). *All other* ***researchers*** *involved must be detailed below.* | | | | | | | | |
| **Name & Qualification** | | **Position & primary employer** | | **Role in research project** | | | **Email Address** | |
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RESEARCH APPLICATION CHECKLIST

Please answer all question yes, no or not applicable as appropriate to the following questions. If you answer no to any question, please explain why and the relevant question number in the comment box at the end of the form.

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| --- | --- | --- | --- |
|  | **YES** | **NO** | **N/A** |
| 1. Are you undertaking the proposed research study in your capacity as a staff member of the *School of Linguistic Speech and Communication Sciences?* |  |  |  |
| 1. Are you undertaking the proposed research study in your capacity as a student of the School of *Linguistic Speech and Communication Sciences?* |  |  |  |
| 1. If you are a student, has your **supervisor read, approved and signed** the completed form? |  |  |  |
| 1. Have you **signed** the application form? |  |  |  |
| 1. Have you **checked** that your application meets the criteria for this research ethics committee? |  |  |  |
| 1. Are you recruiting participants for this study? |  |  |  |
| 1. Are the participants purposefully recruited from a vulnerable group? |  |  |  |
| 1. Is this a health research study? |  |  |  |
| 1. Does the study include a health intervention? |  |  |  |
| 1. Are you collecting personal or sensitive data? |  |  |  |
| 1. Have you **completed** and **included** a risk assessment (for data) for this study? |  |  |  |
| 1. Do you require a Data Protection impact assessment? |  |  |  |
| 1. If applicable (yes to Q8), have you **completed** a Data Protection impact assessment? |  |  |  |
| 1. If accessing personal or sensitive data have you successfully **completed** Trinity GDPR online course? |  |  |  |
| 1. If accessing collecting personal or sensitive data, and if you are an undergraduate or master’s student, has your supervisor successfully **completed** Trinity GDPRonline course? |  |  |  |
| 1. If accessing collecting personal or sensitive data, have all Trinity members of the research team listed, successfully **completed** Trinity GDPR online course? |  |  |  |
| 1. Have you **included** a copy of the questionnaires, interview template, data extraction list? |  |  |  |
| 1. Are you collecting samples, no matter how small, that could be used for genetic testing? |  |  |  |
| 1. If applicable, have you **included** the consent form and participation information leaflet? |  |  |  |
| 1. If applicable, have you **included** all relevant letters of permission /access from external agencies/organisations/ schools/ industry / clinical site hosting the study, from the appropriate responsible people agreeing access included including access to databases? |  |  |  |
| 1. If applicable, have you **included** the letter to the participants? |  |  |  |
| 1. If applicable, have you **included** any posters/other material used to advertise the study? |  |  |  |
| 1. If collecting personal or sensitive data, have you **included** detailed information on how you will implement security measures to protect the personal data in all its forms and all types e.g. device encryption? |  |  |  |
| 1. Have you **included** any other documents that are needed for your study i.e. Garda clearance, debrief documentation? |  |  |  |
| 1. If collection personal or sensitive data do you agree to only use the minimum data necessary to carry out the research? |  |  |  |
| 1. Have you put in all the necessary security arrangements required to collect, process store and destroy any personal or sensitive data required for this study? |  |  |  |
| 1. Are there any contractual arrangement required in order to carry out this study? |  |  |  |
| 1. Have you read and will abide by the requirements regarding research reporting, data storage and reporting of adverse events |  |  |  |

If you have answered NO to any of the above questions (except 1,2,6) please explain:

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**SECTION 2 – DETAILS OF RESEARCH PROJECT AND PARTICIPANT SELECTION**

**2.1** Title of research project and details of any funding body:

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**2.2** Dates & duration of research activities:

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| --- | --- | --- | --- |
| Proposed start date for fieldwork/data collection (please provide specific planned start date which should not precede research ethics approval): |  | Proposed end date of fieldwork/data collection (please provide specific planned end date): |  |

**2.3** What are the primary location(s) for data collection? E.g. classroom, clinic, lab, participants’ home, place of convenience for participants. Researchers conducting fieldwork in participants’ home should ensure they have familiarised themselves with the Lone Researcher Guidelines on the School website.

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**2.4** Please provide a brief outline of the proposed project **(maximum 400 words in total).** This should include aim(s) and objective(s), background, research question(s) or hypothesis, research design.

**(a) Aims/objectives and theoretical background**

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**(b) Research question(s) or hypothesis**

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**(c) Research design. Please briefly describe the project research design/methodology, include your inclusion & exclusion criteria**

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**2.5 Please describe recruitment, sampling and data collection procedures**

**(a)** Please specify exactly how participants will be recruited and what steps you will take to access the sample.

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**(b)** Describe exactly how participants will be contacted and who will make contact at each stage of the study, including information regarding gatekeeper(s) for this study (if applicable).

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**(c)** Please describe expected sample size and composition.

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**(d) Data collection procedures.** Please tick the research instruments you intend to use (ensuring you append copies of each instrument) and (ii) provide an estimation of the time commitment involved for participants/respondents.

(i) *Please tick as many boxes as relevant to your project:*

|  |  |  |  |
| --- | --- | --- | --- |
|  | Questionnaires |  | Video Recordings |
|  | Interviews |  | Observations |
|  | Focus Groups |  | Classroom Intervention |
|  | Audio Recordings |  | Ethnographic Research |
|  | *Other (please specify):* |  |  |

(ii) *Estimation of the time commitment involved for participants:*

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**SECTION 3 – INFORMED CONSENT**

**3.1** Please give details of how information will be provided to participants to ensure that they can make a fully informed decision about participation. Please include a description of who will provide this information. Attach a copy of the Participant Information Leaflet (if the study involves a survey please ensure that all the relevant information to allow participants to make an informed decision about participation is included as the first section of the survey.

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**3.2** Please give details of who will obtain consent from participants and how it will be done. Attach a copy of the consent form. For online surveys where a separate consent form is not used please describe how explicit consent will be sought (e.g. through the participant clicking ‘agree’).

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**3.3** Working with children: will assent be obtained from any children under 18?

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| --- | --- | --- | --- | --- | --- |
| **YES** |  | **NO** |  | **N/A** |  |

Will informed consent be obtained from parents/carers on behalf of any children under 18?

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **YES** |  | **NO** |  | **N/A** |  |

If **YES**, please give details of who will obtain assent from children/consent from parents/carers, and how it will be done. Please attach a copy of any letters, assent/consent form and information leaflet (where appropriate). If verbal assent is sought please attach a script outlining the wording of the request for assent. Please see guidelines on how to prepare these documents on the School website, and adapt the examples provided to suit your study and participants. If **N/A**, please comment.

**3.4** Please specify if you will allow for a time interval between providing your participants with information about the research and seeking their consent: *(For example, in some research methodologies, it is recommended that a period of 3 to 7 days be provided for reflection before asking individuals to participate in an experiment.)*

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**3.5** Will the participants be from any of the following groups (tick as appropriate):

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| --- | --- | --- |
| **PLEASE TICK THE APPROPRIATE BOX** | **YES** | **NO** |
| Children under 18 years of age |  |  |
| Adults with learning disabilities |  |  |
| Adults with language or communication difficulties |  |  |
| Adults who have dementia |  |  |
| Adults with mental illness |  |  |
| Clinical population |  |  |
| Other groups who may be considered vulnerable Please specify below: |  |  |

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**3.6** If participants are to be recruited from any of the potentially vulnerable groups listed above, please give details of:

(a) Any special steps taken to ensure that participants from vulnerable groups are as fully informed as possible about the nature of their involvement:

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(b) Who will give consent:

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(c) How consent will be obtained (e.g. will it be verbal, written or visually indicated?):

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(d) The arrangements that have been made to inform those responsible for the care of the research participants of their involvement in research:

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(e) The use of a gatekeeper in accessing participants

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**3.7**

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| **GDPR Explicit Consent Requirements – Processing of Personal Data** | **Yes** | **No** |
| 1. Is the consent been freely given? Will you inform the data subject that they have the option to withdraw their consent at any time if they so wish? |  |  |
| 1. Is the consent specific (regarding the data to be collected AND how it will be used)? |  |  |
| 1. Is the consent informed? |  |  |
| 1. Is the consent unambiguous (involving a clear affirmative act that is recorded in some way)? |  |  |

**SECTION 4 – CONFIDENTIALITY, DATA PROTECTION, DATA PROCESSING AND DATA STORAGE**

**4.1 Does the study involve collecting, using, accessing or sharing personal data1?**

|  |  |  |  |
| --- | --- | --- | --- |
| **YES** |  | **NO** |  |

If **yes** please give details of the personal data to be collected (Participant identities, contact details, consent forms, code keys that link personal data to other data).

Please specify details for all that apply and likewise for all media forms utilised (online, hard copy, audio etc.). Under Data Protection Law, the collection of personal data is to be kept to a minimum. Please indicate how the personal data being collected relate to the aims and objectives of the study.

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| **Data Collected** | **Justification** | **Processing Activity (including secure storage)** |
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**4.2 Does the study involve collecting, using, accessing or sharing sensitive data?**

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| **Data Collected** | **Justification** | **Processing Activity (including secure storage)** |
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**4.3 Who will control i.e. determine the way in which the personal and sensitive data is used and be responsible for this use? (i.e. data controller or data controllers; this will most likely be an institution like TCD).**

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**4.4 Specify the name/s of any personnel who will have access to the personal and sensitive data? Please identify the affinities and roles of those individuals who are not employees or students of Trinity or their affiliated hospitals or institutes. For other personnel such as data inputters and transcribers see 4.5 (Insert multiple lines for more individuals).**

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| **Personnel Names** | **Nature of data to be accessed** | **Format of data** |
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**4.5 Specify the name/s of any service providers such as transcribers, third parties carrying out analysis, data collection etc.? Indicate below the format in which they will receive the data i.e. original, anonymised, non-anonymised or pseudonymised.**

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| **Personnel Names** | **Nature of data to be accessed** | **Format of data** |
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**4.6 During and after the study, what steps will you take to protect the confidentiality of personal or sensitive personal data collected as part of the project? (e.g. Participant identities, contact details, consent forms, code keys that link personal or sensitive personal data to other data, data collected from patient/client records). Please specify details for all that apply and likewise for all media forms utilised (online, hard copy, audio etc.)**

Please note: Double encryption is required on all computers, laptops and mobiles devices. Personal data should not be stored on portable devices unless absolutely necessary and it should be stated here if this is necessary and why. Cloud storage of personal data require secure clouds as recommended by TCD and if cloud storage is used it should be indicated here

|  |  |  |
| --- | --- | --- |
| **Personal/sensitive date type**  **and media format** | **Format** | **Comments on protection details** |
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**4.7 Please specify how you will record who accesses, changes, discloses or erases all personal data collected.**

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**4.8 If applicable, please indicate clearly when and where pseudo-anonymisation and/or anonymisation and deletion will occur. Please indicate who will be responsible for these processes and who will retain the key code.**

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**4.9 Are there any potential confidentiality issues through identification of the study site?**

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| **YES** |  | **NO** |  | **N/A** |  |

**If yes, please expand.**

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**4.10 Accepted best practice recommends secure retention of personal non-anonymised (of all the types listed previously) for 7 years. If there is any reason to apply for a variation from these guidelines, please give details and provide a justification.**

*Consent forms* ***must*** *be kept for 7 years. If the study has been carried out by a student/students consent forms must be retained by the supervisor. The Participant Information Leaflet must include information regarding the anonymization and destruction of personal and sensitive data and the implications of this i.e. once anonymised cannot be withdrawn.*

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| --- | --- | --- |
| **Personal/sensitive date type**  **and media format** | **Format** | **Retention time & person responsible for destruction/archiving** |
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**4.11 If identifiable data or pseudo-anonymised data or material (recordings, photographs etc.) will be retained after the study is completed, is it stated on the informed consent form that this will be done and that material will not be used in future unrelated studies without further specific permission being obtained?**

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| --- | --- | --- | --- | --- | --- |
| **YES** |  | **NO** |  | **N/A** |  |

**4.12 Researchers must allow the participant access to their data and transcript, if participants wish to view it. Please give details of these arrangements in the PIL.**

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**4.13 Health Research** Is your research classified as health research as defined by the Health Research Regulations (2018), according to any of the component descriptions:

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|  | **Yes** | **No** |
| research aimed at understanding functioning, at molecular, cellular, organ system and whole body levels |  |  |
| research specifically concerned with innovative strategies, devices, products or services for the diagnosis, treatment or prevention of human disease or injury |  |  |
| research aimed at improving the diagnosis and treatment (including the rehabilitation and palliation) of human disease and injury and of improving the health and quality of life of individuals |  |  |
| research aimed at improving the efficiency and effectiveness of health professionals and the health care system |  |  |
| research aimed at improving the health of the population as a whole or any part of the population through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status |  |  |

If you answered ‘Yes’ to any of the above, then you must address section 4.13(a) and 4.13(b) below

**4.14(a) The provision of training in data protection for anyone carrying out health research is mandatory. All researchers and students are expected to have completed the GDPR and Health Research Training to enable them to have permission to assess personals and sensitive data Please provide details of the training undertaken by all named researcher on this application.**

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**4.14(b) To comply with the requirements of the Health Research Regulations 2018, you must carry out the following:**

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| **Please mark with an X to indicate the steps that have been detailed in this application form** | |
| Identify and document the data controllers and data processors. |  |
| Ensure relevant contractual arrangements are in place (e.g. to access participants). |  |
| Identify and document funding bodies of any kind including commercial entities. |  |
| Identify third parties with whom data will be shared even if pseudonymised. |  |
| Ensure all members of the research team who will access personal data have completed data protection training. |  |
| Carry out a Data Protection Impact Assessment (DPIA) if the research is a high risk to individuals or participants. involves the use of genetic data, monitoring of behaviours, large scale processing of sensitive data, use of the data for new purposes or the linking of several datasets. |  |
| Ensure you only use the minimum data necessary to carry out the research. |  |
| Implement controls to ensure the integrity and accuracy of data and determine when the data has been altered, disclosed or erased and by whom. |  |
| Implement security measures to protect the personal data e.g. device encryption. |  |
| Detail a plan to ensure that the data is archived, anonymised or destroyed when the research is completed. |  |
| Ensure that participants are provided with sufficient information about the use of their personal data via participant information leaflets. |  |
| Obtain explicit consent for the processing of personal data for the health research including the screening of individuals for research purposes. |  |

**SECTION 5 – RISK, HARM AND BENEFIT**

**5.1** What is the potential for an adverse outcome for research participants? (For example, inconvenience, physical or emotional risk, discomfort, stress, anxiety, fatigue or embarrassment. In low risk projects, adverse outcomes are usually rare.) NOTE: for the protection of both the researcher and participants, this list must appear in full in the participant information leaflet.

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**5.2** Please indicate what steps you will take in order to minimise any potential adverse outcomes for research participants:

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**5.3** What is the potential for benefit, if any, for research participants?

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**5.4** Will payment be made to research participants?

|  |  |  |
| --- | --- | --- |
|  |  | **YES** |
|  |  | **NO** |
|  |  | **Minimal payment to cover travel cost etc.** |

**5.5** If you answered **YES** to the previous question, please specify for what purpose the payment will be made and the amount per participant:

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**5.6** Are you aware of any conflicts of interest that could arise in the course of this project? If your answer is **YES**, please give full details below:

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**5.7** Are there any other ethical considerations which you anticipate in relation to your study that have not been covered by the questions above? If so, what steps will you take to address these?

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**SECTION 6 – ETHICAL APPROVAL FROM OTHER COMMITTEES**

**Ethical approval from the School of Linguistic, Speech & Communication Sciences Research Ethics Committee, if granted, does not supersede any requirements that external organisations may have regarding additional applications for ethics being made to local ethics committees in advance of the commencement of the study.**

**6.1** Has ethical approval been sought from any other organisation(s) in which the study will place?

|  |  |  |
| --- | --- | --- |
| YES |  | (If you answer YES go to question 6.2) |
| NO |  | (If you answer NO go to question 6.3) |
| N/A |  | (If N/A please explain why below) |

**6.1(a)** If you have answered YES to question 6.1, from where has approval been sought and has ethical approval been granted? Please give the name of ethics committee, the application reference number, date of application, date of approval and any amendments that were requested by the granting committee. If a DPIA was required for this application please insert it as an appendix to this application.

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**6.2**  Has approval been granted from any other institution?

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| **YES** | **Awaiting Reply** | **NO** | **IF NO, PLEASE EXPLAIN WHY (NA 0R EXPLANATION)** |
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**6.3** If you have answered NO to question 6.1, is it your intention to seek ethical approval from the organisation(s) in which the study will take place?

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| **YES** | **NO** | **IF NO, PLEASE EXPLAIN WHY** |
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**SECTION 7 – CONFIRMATION OF APPLICANT AND SUPERVISOR DECLARATIONS**

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| **APPLICANT DECLARATION:** I confirm that the information provided in this form is correct, that I am not aware of any other ethical issues not addressed within this form. I understand the obligations to and the rights of participants (particularly concerning their safety and welfare, the obligation to provide information sufficient to give informed consent and the obligation to respect confidentiality). | |
| **APPLICANT CONFIRMATION OF DECLARATION:** |  |
| **APPLICANT NAME:** | **DATE:** |

|  |  |
| --- | --- |
| **RESEARCH SUPERVISOR CONFIRMATION OF DECLARATION :**  Student applicants are required to have their Research Supervisor complete this section. Research Supervisors are also required to send an email to the Research Ethics Committee confirming that they have reviewed the ethics application and that the proposed research project conforms to the School’s Research Ethics Guidelines. | |
| **SUPERVISOR DECLARATION:** As the student’s supervisor, I have read this document, and to the best of my knowledge, this project conforms to the School’s Research Ethics Guidelines. | |
| **SUPERVISOR CONFIRMATION OF DECLARATION:** |  |
| **SUPERVISOR SIGNATURE:** | **DATE:** |

**REMEMBER TO:**

* **INCLUDE ANY APPENDICES**
* **ENSURE YOUR SUPERVISOR HAS SIGNED THE FORM**
* **RETURN IN A SINGLE PDF FILE TO:** [**slscs@tcd.ie**](mailto:slscs@tcd.ie)