

TUS RESEARCH ETHICS FORM : RE1

***For Applicant to complete:***

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| --- | --- |
| **Appicants Name:** |  |
| **Title of Project:** |  |

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| --- |
| ***For Ethics Committee use only:*** |
| **Reference Number:**   |
| **Date Received:** |
| **Review Date:** |
| **Applicant informed Date:** |
| **OUTCOME** |  |
| **No Ethical Issues Flagged** |[ ]
| **Approval**  |[ ]
| **Approved with modifications – no resubmission required** |[ ]
| **Approved with modifications - resubmission required** |[ ]
| **Deferral, additional information required** |[ ]
| **Approval Declined** |[ ]

***Please complete form and select YES/NO options as appropriate. An electronic version of this form is also available on the website:* as appropriate**

**TUS Midlands:**

Ethics@tus.ie

**TUS Midwest**

https://studentlit.sharepoint.com/Staff/Academic/Graduate/SitePages/Postgraduate%20&20Research%20Forms.aspx

An application will **only be accepted** for review by the relevant (Faculty/Research *as appropriate*) Ethics Sub-Committees if it is completed fully and the relevant enclosures/attachments/signatures are received. Refer to the accompanying Guidance Notes when completing the form and complete the checklist on the next page before submitting the form. Where you have received permission to do this, or similar research in another institution, please provide evidence of permission with this application.

**Address to send application*:* as appropriate**

**TUS Midlands:**

Ethics@tus.ie

**TUS Midwest**

graduatestudies@tus.ie

|  |
| --- |
| **CHECK LIST** |
| Have you included all Signatures? | [ ]   |
| Have you addressed every Question or inserted N/A as applicable | [ ]   |

Select all descriptors that apply to this study:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Healthy volunteer |[ ]   | Cross-over |[ ]   | Biological material |[ ]
| Patient volunteer |[ ]   | Case-study |[ ]   | Foetal material |[ ]
| Vulnerable participants |[ ]   | Longitudinal |[ ]   | Hazardous materials |[ ]
| Children (under 18 yrs) |[ ]   | Cross-sectional |[ ]   | Invasive procedures |[ ]
| Children (under 16 yrs) |[ ]   | Placebo |[ ]   | Devices (in licence) |[ ]
| Observational |[ ]   | Therapeutic |[ ]   | Medicinal products  |[ ]
| Interview |[ ]   | Controlled |[ ]   | (in licence) |  |
| Questionnaire |[ ]   | Double-blind |[ ]   | Devices |[ ]
| Record-based |[ ]   | Single-blind |[ ]   | (outside licence) |  |
| Randomised |[ ]   | Prospective |[ ]   | Medicinal products  |[ ]
| Non-randomised |[ ]   | Retrospective |[ ]   | (outside licence) |  |
| Plant |[ ]   |  |  |  |

**Other** (please state)

**Research Activity Prohibited at TUS (Art. 6 EC Commission 1982/2006/EC)**

1. Research activity aiming at human cloning for reproductive purposes
2. Research activity intended to modify the genetic heritage of human beings which could make such changes heritable.
3. Research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.
4. Research activity on animals.

**Section 1:**

Please complete all parts of Section 1 - Enter N/A if not applicable.

|  |  |
| --- | --- |
| **1.** | **Applicant’s Name:** |
| **1.1** | **School/Faculty:** | **Department:** |
| **1.2** | **Research Centre or Group:** |
| **1.3** | **Principal Supervisor:** |
| **1.4**  | **Award Sought:** | *M.A.* | *M.Bus.* | *M.Eng.* | *M.Sc.* | *Ph.D.* |
|  |  | [ ]   |[ ] [ ] [ ] [ ]
| **1.5** | **Title of Proposed Research** |
| **1.6** | **Research Question** |
| **1.7**  | **Proposed Programme of Research (in the form of an abstract up to 500 words)** |
| **1.8** | **Applicant’s Signature:** | **Date**: Click or tap to enter a date. |
| **1.9**  | **Principal Supervisor’s Signature:** | **Date**: Click or tap to enter a date. |

**Section 2: Identification of Ethical Issues – to be completed by Principal Supervisor**

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| * 1. **Research on Humans**
 | **YES** | **NO** |
| Please note: 1. Any research involving human research participants may not commence until a further application by the researcher/s detailing the rationale for the research and details of the procedures that will be followed has been approved by the Research Ethics Committee.
2. You are required to initiate the process for Garda Vetting if your research involves working with vulnerable adults or those under 18 years of age.
 |
| Does the proposed research involve adult healthy volunteers **(including conducting surveys)**?  | [ ]  | [ ]  |
| Does the proposed research involve children (under 18 years of age)? | [ ]  | [ ]  |
| Does the proposed research involve children (under 16 years of age)? | [ ]  | [ ]  |
| Does the proposed research involve patients? | [ ]  | [ ]  |
| Does the research involve vulnerable people? | [ ]  | [ ]  |
| Does the proposed research involve persons not able to give consent? | [ ]  | [ ]  |

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| **2.2 Privacy/Personal Data** | **YES** | **NO** |
| Does the proposed research involve the collection and storage of personal data? | [ ]  | [ ]  |
| Does the proposed research involve processing of genetic information or personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)? | [ ]  | [ ]  |
| Does the proposed research involve tracking the location or observation of people (audio/visual recording)? | [ ]  | [ ]  |
| **Please note: Details of procedures relating to the collection and storage of data, confidentiality, anonymity and rights to withdraw should be submitted by the researcher/s along with the application to proceed with data collection.**  |

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| **3. Research on Human Genetic Material** | **YES** | **NO** |
| Does the proposed research involve Human genetic material? | [ ]  | [ ]  |
| Does the proposed research involve Human biological samples? | [ ]  | [ ]  |

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| **4. Research on Human or Animal Subjects** | **YES** | **NO** |
| Does the proposed research involve the use of a new medical product or medical device, or the use of an existing product outside the terms of its product licence? | [ ]  | [ ]  |
| Does the proposed research involve the use of ionizing or non-ionising radiation, radioactive substances or X-Rays. A competent Radiation Protection Advisor must be involved in implementing this section? | [ ]  | [ ]  |

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| **5. Research on Human Embryo/ Foetus** | **YES** | **NO** |
| Does the proposed research involve human Embryos? | [ ]  | [ ]  |
| Does the proposed research involve human Foetal Tissues/ Cells? | [ ]  | [ ]  |
| Does the proposed research involve human Embryonic Stem Cells (hESCs)? | [ ]  | [ ]  |
| Does the proposed research on human Embryonic Stem Cells involve cells in culture? | [ ]  | [ ]  |
| Does the proposed research on Human Embryonic Stem Cells involve the derivation of cells from Embryos? | [ ]  | [ ]  |

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| **6. Research on Animals** | **YES** | **NO** |
| Does the proposed research involve research on animals? | [ ]  | [ ]  |
| Are those animals transgenic small laboratory animals? | [ ]  | [ ]  |
| Are those animals transgenic farm animals? | [ ]  | [ ]  |
| Are those animals non-human primates? | [ ]  | [ ]  |
| Are those animals cloned farm animals? | [ ]  | [ ]  |

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| **7. Research Involving Developing Countries**  | **YES** | **NO** |
| Does the proposed research involve the use of local resources (genetic, animal, plant, etc)? | [ ]  | [ ]  |
| Is the proposed research of benefit to local communities (e.g. capacity building, access to healthcare, education, etc.)?  | [ ]  | [ ]  |

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| **8. Dual Use**  | **YES** | **NO** |
|  Research having direct military use  | [ ]  | [ ]  |
|  Research having the potential for terrorist abuse | [ ]  | [ ]  |

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| 1. **Other Ethical Issues**
 | **YES** | **NO** |
| Are there **OTHER** activities that may raise **Ethical Issues**?  | [ ]  | [ ]  |
| If **YES** please specify: |   |   |
|       |

**Note: If you answer yes to the any of the questions above, a full application for ethical approval must be referred to the relevant TUS (Faculty/Research *as appropriate*) Ethics Committee**

**Section 3: Declarations**

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| **Signed Declarations****Supervisor** (To be completed in cases where the applicant is a research postgraduate student.)  |
| I hereby declare that I have read, understood and agree to abide by the TUS Ethics Policy for Researchers. I also authorise the Principal Investigator named above to conduct this research project in accordance with the requirements of TUS Ethics Policy for Researchers. I have informed the Principal Investigator of their responsibility to adhere to the recommendations and guidelines in set out in the TUS Ethics Policy for Researchers.**Supervisor Signature : Date:** Click or tap to enter a date. **Print Name : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Investigator** |
| The information contained in this application form is accurate to the best of my knowledge and belief. I have:* Read the most recent TUS Ethics Policy for Researchers.
* Agreed to abide by the TUS Ethics Policy for Researchers in conducting this research.
* Accepted without reservation that it is my responsibility to ensure the implementation of the policies outlined in the TUS Ethics Policy for Researchers.
* Undertaken to inform the TUS Ethics Committee of any changes in the protocol.
* Understood that it is my sole responsibility and obligation to comply with all domestic Irish and European legislation and to obtain such statutory consents as may be necessary.
* Agreed not to commence any research until any such consents have been obtained.
* Understood that neither the University, the Committee, nor individual members of the Committee accept any legal obligation (to me 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.

 **Researcher’s** **Signature : Date:** Click or tap to enter a date. **Print Name : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

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**Section 4 – Conclusion by the Research Ethics Committee**

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| --- | --- | --- |
| **Conclusion** | **YES** | **NO** |
| **No Ethical Issues Flagged** | ☐ | ☐ |
| **Approval**  | ☐ | ☐ |
| **Approved with modifications** | ☐ | ☐ |
| **Deferral, additional information required** | ☐ | ☐ |
| **Approval Declined** | ☐ | ☐ |
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**Chair (Faculty *as appropriate)* Ethics Committee: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **Date:** Click or tap to enter a date.

Approval Reference Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**References**

[Research and innovation | European Commission (europa.eu)](https://ec.europa.eu/info/research-and-innovation_en)

**EU Research Legislation, Rights and Standards**

Including:

Research Participants – Informed Consent

Research Participants – Under 18

Privacy

Data Protection Guidelines

Dual Use

[Research (who.int)](https://www.who.int/health-topics/research#tab=tab_1)

**WHO Research Standards and Legislation**

[Patient Consent - HSE | Research & Development (hseresearch.ie)](https://hseresearch.ie/patient-consent/)

**HSE National Consent for Research Policy**

[Open Disclosure - HSE.ie](https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/open-disclosure/)

[Assisted Decision-Making (Capacity) Act (2015) - HSE.ie](https://www.hse.ie/eng/about/who/national-office-human-rights-equality-policy/assisted-decision-making-capacity-act/)

**Assisted Decision Making**