

TUS RESEARCH ETHICS FORM : RE2

***For Applicant to complete:***

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

|  |
| --- |
| ***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** |[ ]
| **Application referred to TUS Research Ethics Committee**  |[ ]

***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 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.

**Please ensure that all copies relevant to this application are collated together: application form, proposal, participant consent form(s), patient information sheet(s) and Questionnaire(s).**

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

**TUS Midlands:**

Ethics@tus.ie

**TUS Midwest**

graduatestudies@tus.ie  **SUBMISSION Checklist**

Please indicate if the following have been enclosed by selecting YES/NO/Not applicable options below. Please forward copies of the form and relevant enclosures required as outlined below.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **Not Applicable** |
| Electronic Copy of Completed Application.  |[ ] [ ] [ ]
| Insert File Name here: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Research Proposal Summary (No more than 750 words) |[ ] [ ] [ ]
| Participant assent / consent form(s) |[ ] [ ] [ ]
| Participant information sheet(s) |[ ] [ ] [ ]
| Questionnaire(s); surveys etc.  |[ ] [ ] [ ]
| Sample email, letters (GP, Recruitment etc.) |[ ] [ ] [ ]
| Copy of Risk Assessment Form\*(if this study required RA has this been completed) |[ ] [ ] [ ]
| Copy of Principal Investigators CV (2 A4 pages max) Previously submitted |[ ] [ ] [ ]
| Annex 1\* |[ ] [ ] [ ]
| Annex 2\*\* |[ ] [ ] [ ]
| Annex 3\*\*\* (1 copy per procedure for which risk identified) |[ ] [ ] [ ]
| Annex 4 – Consent Form |[ ] [ ] [ ]

*\* If the study involves the use of a new medicinal product or medical device, or the use of an existing product outside the terms of its product license*

*\*\* If the study includes the use of ionizing or non-ionising radiation, radioactive substances or X rays*

*\*\*\* Please complete for each hazardous procedure*

|  |
| --- |
| **SUMMARY CHECK LIST** |
| Have you included all Signatures? |[ ]
| Have you addressed every Question or inserted N/A as applicable |[ ]
| Acknowledge power dynamics and elaborate how you will address the power dynamics that may exist between researcher and participants. The researcher should demonstrate how they accounted for this. |[ ]
| Specify a time period for right to withdraw: it is not wise to offer a blanket right to withdraw, instead offer the right to withdraw anytime **during** the focus group and/or then a specified period after the data is collected. |[ ]
| Specify the duration that data will be stored for. The data will need to be securely stored in a digital format on TUS OneDrive. |[ ]

STUDY DESCRIPTORS

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 Applicant(s) Details

**1. Title of project:**

|  |
| --- |
|  |

**2. Principal Investigator:** *(All correspondence will be sent to this address unless indicated otherwise.)*

|  |  |
| --- | --- |
| **Family Name:** |  |
| **Forename:** |  |
| **Title:** |  |
| **Address:** |  |
| **Phone Number:** |  |
| **Mobile Number:** |  |
| **Email address:** |  |
| **Present appointment of PI:** |  |
| **Qualifications of PI:** |  |

**3. Other Investigator(s):**

|  |  |
| --- | --- |
| **Family Name:** |  |
| **Forename:** |  |
| **Title:** |  |
| **Faculty/Department/School:** |  |
| **Institution:** |  |
| **Phone Number:** |  |
| **Email address:** |  |
| **Present Appointment**  |  |
| **Qualifications** |  |

|  |  |
| --- | --- |
| **Family Name:** |  |
| **Forename:** |  |
| **Title:** |  |
| **Faculty/Department/School:** |  |
| **Institution:** |  |
| **Phone Number:** |  |
| **Email address:** |  |
| **Present Appointment**  |  |
| **Qualifications** |  |

|  |  |
| --- | --- |
| **Family Name:** |  |
| **Forename:** |  |
| **Title:** |  |
| **Faculty/Department/School:** |  |
| **Institution:** |  |
| **Phone Number:** |  |
| **Email address:** |  |
| **Present Appointment**  |  |
| **Qualifications** |  |

**4. Other workers and Faculty/School/Departments/Institutions involved:**

|  |  |
| --- | --- |
| **Family Name:** |  |
| **Forename:** |  |
| **Title:** |  |
| **Faculty/Department/School:** |  |
| **Institution:** |  |
| **Phone Number:** |  |
| **Email address:** |  |
| **Present Appointment**  |  |

|  |  |
| --- | --- |
| Independent Contact Name:  |  |

5. Funding Sources:

**(i) Has any funding been obtained/sought by the investigator in respect of this study?**

|  |  |  |  |
| --- | --- | --- | --- |
| Funding applied for:  | Yes [ ]  | No [ ]  | Not applicable [ ]  |
| Funding Secured | Yes [ ]  | No [ ]  | Not applicable [ ]  |

**(ii) Name of sponsoring organisation from which funding has been obtained/sought?**

|  |
| --- |
|  |

**(iii) Does the Investigator(s) have any direct involvement in the sponsoring organisation?**

|  |  |  |  |
| --- | --- | --- | --- |
| e.g. financial, share-holding etc:  | Yes [ ]  | No [ ]  | Not applicable [ ]  |

**If YES, give details:**

|  |
| --- |
|  |

**NOTE: Where the research programme has already received funding approval, please attach the letter of offer to this application.**

**6. Proposed start date and duration of study:**

|  |  |
| --- | --- |
| **Proposed Start Date:**  |  |
| **Duration (Months):** |  |

**7. Signature of relevant personnel:**

**Principal Investigator declaration – For Postgraduate Research**

*The information in this application form is accurate to the best of my knowledge and belief and I take full responsibility for it.*

*I understand that it is my responsibility to obtain institutional approval where appropriate before the project takes place.*

*I agree to supply interim and final reports to the Research Ethics Committee from which approval was granted for this project.*

*I agree to advise the Research Ethics Committee from which approval was granted for this project and any local researchers taking part in the proposal of any material changes to the proposal or any adverse or unexpected events that may occur during this project.*

*I agree to advise the Research Ethics Committee in the event of premature termination, suspension or deferral of this project and to provide a report outlining the circumstances for such termination, suspension or deferral.*

**Signature of Principal:**

**Date**: Click or tap to enter a date.

**Co-Signed by Supervisor where the P.I. is a Student:**

**Date:** Click or tap to enter a date.

**Head of Faculty/School/Institution/Supervisor**

*I am fully aware of the details of this project and agree for it to continue as outlined here. I can confirm that the necessary facilities and resources are available to the researcher.*

|  |  |
| --- | --- |
| **Name:** |  |
| **Department:** |  |

**Signature**: **Date**: Click or tap to enter a date.

(Email confirmation or electronic signatures are also accepted)

SECTION 2 Study Details

**Independent Contact Name – For Staff and External Research**

*Can you confirm you have obtained agreement from your independent contact for any issues or complaints that may arise from research participant’s. Yes* [ ]  *No*[ ]

*This person will appear as a contact on your participant information sheet in case of a query or complaint that research participants may wish not to address to you as the researcher.*

**Signature of Applicant: Date**: Click or tap to enter a date.

(Email confirmation or electronic signatures are also accepted)

*This section must be completed. A copy of the protocol should be enclosed with the application form but it is* ***not*** *sufficient to complete questions by referring to the protocol.*

**8. Research Output – Postgraduate Researcher (**i.e. what is the intention of the study, key research questions?)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Award Sought:** | *M.A.* | *M.Bus.* | *M.Eng.* | *M.Sc.* | *Ph.D.* |
|  |  |[ ] [ ] [ ] [ ] [ ]
| **For Staff or External Researchers:****Research Output:** |

**9. Aim and objectives of study (**i.e. what is the intention of the study, key research questions?)

|  |
| --- |
|  |

**10. Scientific/theoretical background[[1]](#footnote-1) to study** (Approx. 250 words)

|  |
| --- |
|  |

**11. Brief plan of investigation[[2]](#footnote-2)** (i.e. what do you intend to do?) (Approx. 250 words)

|  |
| --- |
|  |

12. List procedures or investigations involving risks to participants’ well-being or safety (what, when, how often and risks associated with all procedures)

|  |
| --- |
|  |

13. Does the study fall into any of the following categories?

|  |  |  |  |
| --- | --- | --- | --- |
| Pilot:  | Yes [ ]  | No [ ]  | Not applicable [ ]  |
| Multi-Centre study: | Yes [ ]  | No [ ]  | Not applicable [ ]  |

***If this is a multi-centre study, please complete the following details, otherwise go to question 14.***

(i) Which centres are involved?

|  |  |
| --- | --- |
| Contact Name: |  |
| Department / Centre: |  |

(ii) Which ethics committees have been approached, and what is the outcome to date?

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| --- |
|  |

**(iii) Who will have overall responsibility for the study?**

|  |
| --- |
|  |

14. Study design (tick as appropriate)

|  |  |  |
| --- | --- | --- |
| Survey / Questionnaire |[ ]  *Interviews* |  |
| Case Study |[ ]  * individual
 |[ ]
| Observational |[ ]  * group
 |[ ]
| Action Research |[ ]  * Person-to-person
 |[ ]
| Record based |[ ]  * Telephone
 |[ ]
| Cohort |[ ]  * electronic
 |[ ]
| Case Control |[ ]  *Forms of recording* |  |
| Other – *Please specify**please specify – please include here any external statistical or data repositories that you propose to rely on. Please be conscious that the database must itself reflect sounds research ethics).*  |[ ]  * Video
 |[ ]
| * Audio
 |[ ]
| * Photography
 |[ ]
| * Notes
 |[ ]
| * Electronic recording
 |[ ]

15. Size of the study (including controls):

(i) How was the size of the study determined?

|  |
| --- |
|  |

(ii) Was there formal statistical input into the overall study design? YES [ ]  NO [ ]

(iii) What method of analysis will be used?

|  |
| --- |
|  |

16. Where will the study take place and in what setting?

|  |
| --- |
|  |

**17. Does the study involve:**

|  |  |  |
| --- | --- | --- |
| **(i) distribution of data collection tools?**  | Yes [ ]  | No [ ]  |
| If YES, please append a copy of the questionnaire to this application. Please indicate whether the appended questionnaire, survey, etc. is:  | Non validated: [ ]  | Validated [ ]  |
| **(ii) the use of an existing medicinal product or medical device?** | Yes [ ]  | No [ ]  |
| If YES, is this medical product or device being used within the terms of its current product license? If NO, please complete **Annex 1** of this application. | Yes [ ]  | No [ ]  |
| **(iii) the use of a new medicinal product or medical device?** | Yes [ ]  | No [ ]  |
| If YES, please complete Annex 1 of this application. |  |  |
| **(iv) the use of ionising or non-ionising radiation, radioactive substances or X rays?** | Yes [ ]  | No [ ]  |
| If YES, please complete **Annex 2** of this application. |  |  |

**18. Peer Review/Critique[[3]](#footnote-3)**

**Has the research protocol been subject to external peer review?** YES [ ]  NO [ ]

If the review formed part of the process of obtaining funding, please give the name and address of the funding organisation:

|  |
| --- |
|  |

If the review took place as part of an internal process, please give brief details:

|  |
| --- |
|  |

If no review has taken place, please explain why and offer justification for this:

|  |
| --- |
|  |

SECTION 3 Recruitment of participants

**19. Who is being studied?**

If vulnerable persons are being studied, please give details of reasons for non-competence

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| --- |
|  |

**20. How will be the participants in the study be:**

(i) Selected?

|  |
| --- |
|  |

(ii) Recruited? (Please append advertisement materials to application)

|  |
| --- |
|  |

**21. What criteria will be used for inclusion and exclusion of participants?**

|  |  |
| --- | --- |
| (i) Inclusion criteria: |  |
| (ii) Exclusion criteria: |  |

**22. How many participants will be recruited and of category?**

|  |  |
| --- | --- |
| **Category** | **Numbers** |
| Healthy Adult |  |
| Children under 17-16 years of age |  |
| Children under 16 years of age |  |
| People who have language difficulty |  |
| People who have a recognised or diagnosed intellectual or mental impairment |  |
| People confined to institutions *(prisoners, residents in 24 hour nursing facilities)* |  |
| Persons in unequal relationships with the researcher *(teacher/student; therapist/client; employer/employee)* |  |
| Others *(please specify)* |  |

**23 Is there a Control Group**

YES: [ ]  NO: [ ]

*If NO, please move to Q27*

**24. If applicable, how will the control group in the study be:**

(i) Selected?

|  |
| --- |
|  |

(ii) Recruited? (please append advertisement materials to application)

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**25. What criteria will be used for inclusion and exclusion of the control group?**

|  |  |
| --- | --- |
| (i) Inclusion criteria: |  |
| (ii) Exclusion criteria: |  |

**26. If applicable, how many controls will be recruited and of what category?**

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| --- |
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**27. To your knowledge, are the participants/controls included in this study involved in any other research investigation at the present time?**

 YES: [ ]  NO: [ ]

If YES, please give details

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**28. Will participants receive any payment or other incentive to participate?**

 YES: [ ]  NO: [ ]

1. If YES, give details of incentive per participant?

|  |
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If YES, what is the source of the incentive?

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| --- |
|  |

**Please Summarise the Ethical Issues Identified**

**Please answer all questions – enter N/A if not applicable.**

|  |  |
| --- | --- |
| **What is the benefit that will accrue from this research?** |  |
| **Account for the balance between beneficial effects and potential harms / negative effects of the research?** |  |
| **Does your research activity require the permission/co-operation of a gatekeeper? Please explain:** |  |

|  |
| --- |
| **If participants belong to any of the following vulnerable groups please give details.**[ ]  Children under 18 years of age*.*[ ]  People who have language difficulty[ ]  People who have a recognised or diagnosed intellectual or mental impairment[ ]  People confined to institutions *(prisoners, residents in 24 hour nursing facilities)*[ ]  Persons in unequal relationships with the researcher *(teacher/student; therapist/client; employer/employee)*[ ]  Others *(please specify)*Details: |

|  |
| --- |
| Where participants belong to any of the vulnerable groups listed above, please confirm you have undergone Garda Vetting (or equivalent process). |
|  |

SECTION 4 Consent

**29. Is written consent for participation in the study to be obtained?**

*It is only in highly exceptional circumstances that written consent could be avoided or not required. Justification for collection of personal / survey / participant data without consent will need to be clearly explained and justified in the section below.*

 YES: [ ]  NO: [ ]

If YES, please attach a copy of the consent form to be used *(Guidance on consent is given in the Guidance Notes)*

If NO written consent is to be obtained, please explain why

|  |
| --- |
|  |

**30. How long will the subject have to decide whether to take part in the study?**

*Reasonable timeframes would be expected to be up to 4 weeks; If less than 24 hours, please justify*

|  |
| --- |
|  |

**31. Does the study include participants for whom English is not a first language?**

 YES: [ ]  NO: [ ]

If YES, give details of special arrangements made to assist these participants

|  |
| --- |
|  |

**32. Please attach a copy of the written participant information sheet – Draft template in Annex 4**

If NO information sheet is to be given to participants, please justify

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|  |

**33. If you are recruiting from a vulnerable groups (Children under 16 years of age; People with learning difficulties; Unconscious or severely ill participants; Other vulnerable groups e.g. dementia, psychological disorders, etc.), please specify and justify**

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|  |

(ii) What special arrangements have been made to deal with the issues of consent and assent for vulnerable participants e.g. is parental or guardian agreement to be obtained, and if so in what form?

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(iii) In what way, if any, can the proposed study be expected to benefit the individual who participates?

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**34. Please answer this question only where invasive or other interventions are planned which could be a risk to a pregnancy**

**Are women of childbearing potential included in this study?**

 YES: [ ]  NO: [ ]

If YES, does the protocol/participant information sheet address the following:

* scientific justification
* negative teratogenic studies
* warning participants that foetus may be damaged
* requirement for initial negative pregnancy test
* forms of contraception defined
* duration of use to exceed drug metabolism
* exclude those unlikely to follow contraceptive advice
* notify investigator if pregnancy suspected

If NO, please explain

|  |
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SECTION 5 Details of Interventions

**35. Does the study involve the use of a new medicinal product or medical device, or the use of an existing product outside the terms of its product license?**

 YES: [ ]  NO: [ ]

*If NO, please move to Section 6*

*If YES, please complete this section and Annex 1 of the Application Form.*

**36. Does the study involve investigations and/or interventions on either participants or controls?**

(Please tick YES/NO as appropriate. If YES, details should be available in the protocol)

|  |  |  |
| --- | --- | --- |
| **Investigation/Intervention** | YES |[ ]  NO |[ ]
| Self completion questionnaires | YES |[ ]  NO |[ ]
| Interviews/interview administered questionnaires | YES |[ ]  NO |[ ]
| Video/audio tape recording | YES |[ ]  NO |[ ]
| Physical examination | YES |[ ]  NO |[ ]
| Internal physical examination | YES |[ ]  NO |[ ]
| Venepuncture[[4]](#footnote-4)\* | YES |[ ]  NO |[ ]
| Arterial puncture\* | YES |[ ]  NO |[ ]
| Biopsy material\* | YES |[ ]  NO |[ ]
| Other tissue/body sample\* | YES |[ ]  NO |[ ]
| Imaging investigation (not radiation) | YES |[ ]  NO |[ ]
| Other investigations not part of normal care | YES |[ ]  NO |[ ]
| Additional out patient attendance | YES |[ ]  NO |[ ]
| Longer inpatient stays | YES |[ ]  NO |[ ]
| Local anesthesia | YES |[ ]  NO |[ ]
| General anesthesia | YES |[ ]  NO |[ ]

Other – please detail

|  |
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|  |

Please indicate and justify where treatment is withheld as a result of taking part in the project.

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**37. Will any ionising or non-ionising radiation, or radioactive substances or X-Rays be administered to a participant?**

 YES: [ ]  NO: [ ]

*If YES, please compete Annex 2 of the Application Form.*

**38. Where research is conducted in a primary health care environment, will all GPs whose patients will be involved, be required to sign to indicate that they are aware of and in agreement with the planned project?**

YES: [ ]  NO: [ ]  Not applicable: [ ]

If NO, please explain why not

|  |
| --- |
|  |

SECTION 6 Risks and ethical problems

**39. Are there potential risks of physical injury or prejudice to the health of participants, that may need to be managed outside of the standard and existing policies and protocols for health and safety that operate in our laboratory, workshop and other learning and research spaces (including Researcher)?**

 YES: [ ]  NO: [ ]

*If NO, please move to Section 7*

If YES, please complete **Annex 3** for each procedure for which a potential risk occurs.

**40. Have you taken into consideration the public health advice regarding protecting your safety and the safety of others.** Please include your assessment of any potential risks to the researcher, and what measures will be put in place to ensure the safety of the researcher

 YES: [ ]  NO: [ ]

**If Yes please explain**

|  |
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|  |

**If No why has this not been addressed**

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| --- |
|  |

**41. Is this study likely to cause any discomfort or distress, either physical or mental?**

 **Physical:** YES: [ ]  NO: [ ]

 **Mental:** YES: [ ]  NO: [ ]

If YES, estimate the degree and likelihood of discomfort or distress entailed and the precautions to be taken to minimise them. **Please include other potential embarrassments to the subject that should be explained prior to obtaining consent (e.g. state of undress etc)**

|  |
| --- |
|  |

**42. Are treatments/supports/counseling required for this research?**

 YES: [ ]  NO: [ ]  Not applicable: [ ]

If Yes will this be provided…

during the study: YES:[ ]  NO: [ ]  Not applicable: [ ]

at the end of the study: YES: [ ]  NO: [ ]  Not applicable: [ ]

(ii) If NO, is this made clear in the participant information sheet?

 YES: [ ]  NO: [ ]

If NO, please give reasons

|  |
| --- |
|  |

(iii) What processes will be put in place for de-briefing participants?

|  |
| --- |
|  |

(iv) What support measures are available for participants and how will these be communicated?

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| --- |
|  |

SECTION 7 Plants

**43. Does your research involve research on Plants?**

 Yes [ ]  No [ ]

If No proceed to **Section 8**

**44. Explain the lack of alternative solutions to the research project.**

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|  |

**45. Does your research involve protected plant species and/or protected areas?**

 Yes [ ]  No [ ]

If Yes :

1. Explain the protected species and/or areas involved? Include relevant documented proof that your research is permitted on protected species and/or in protected areas

|  |
| --- |
|  |

1. Will your research require the collection of material such as plants, fungi in protected areas?

 Yes [ ]  No [ ]

**46. Will the research project require the destruction of soils?**

Yes [ ]  No [ ]

If Yes :

1. Explain the extent of this destruction and how it is minimised and reversed were possible

|  |
| --- |
|  |

**47. Provide information concerning any possible risk caused by your research which affects the natural environment or plants**

|  |
| --- |
|  |

**48. Will the research require the use of factors or conditions that may be hazardous to humans, including the research staff?**

 Yes [ ]  No [ ]

If the answer is “YES,”

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| will the research use hazardous chemicals? |[ ] [ ]
| will the research use hazardous physical factors? |[ ] [ ]
| will the research involve biological material that may be hazardous for the research team, e.g. pathogens? |[ ] [ ]
| do the researchers hold certificates from the providers of plants to confirm that they are pathogen-free |[ ] [ ]
| will the plants be tested for pathogens (if applicable)? |[ ] [ ]

(Explain the selection of each of the above aspects of your research)

|  |
| --- |
|  |

SECTION 8 Insurance

**Overview**

TUS holds insurance policies to cover claims for negligence arising from the conduct of the institution’s normal business. This includes research undertaken by undergraduate and postgraduate students as part of their academic qualification as well as research carried out by staff.

If you are a postgraduate student or staff researcher at the institution, you must complete all relevant sections of the checklist on the following pages to identify whether your application requires referral to the university’s Research Office.

Completing and submitting the checklist will ensure that your research study has appropriate insurance cover in place **before** it begins. Please submit your completed Research Insurance Checklist along with your Ethics Application for Ethical Approval to **as appropriate**

**TUS Midlands:**

Ethics@TUS.ie

**TUS Midwest**

graduatestudies@TUS.ie

**Referral to the Insurance Officer**

If your research falls into any of the categories listed in Part 2 and/or Part 3 of the checklist, the Research Officewill send the following information to the Insurance Officer.

* Insurance Checklist
* Ethics Application for Ethical Approval Form
* Participant Information Sheet(s) (if applicable)
* Participant Consent Form(s) (if applicable)
* Risk Assessment

The Research Office will liaise with the insurers to gain approval. Please note some types of research may require additional insurance, including Travel insurance which may incur an additional cost to the Faculty.

**Research studies must not commence until insurance and all other relevant authorisations and/or approvals are given.**

**High Risk Countries**

Please visit the [Red24 website](https://www.red24.com/affiliates/marsh) to identify whether the overall rating for the country you are travelling to is ‘High Risk’ or more severe. Please contact your Faculty Research Officer for guidance on accessing the relevant information on the website.

**ADMINISTRATIVE DETAILS**

|  |  |
| --- | --- |
| **Lead Researcher Name** **(Title/Forename/Surname)** |  |
| **Contact Email Address**  |  |
| **Full Title of the Research** |  |

**Part 1: TECHNIQUES, TESTING AND INTERVENTIONS**

Does your research study involve:

[ ]  **Physically invasive techniques?**

This refers to any test in which the skin of the participant is broken or an implement is inserted into any opening of the human body (e.g. eyes, ears, nose, mouth, lungs, stomach, rectum, vagina and urethra) or involves the taking of body samples such as saliva, hair, urine, faeces, sputum, skin, nails, or taking biopsies of any form for any purpose, or any form of scanning such as DEXA scans, Ultrasound scans, MRI, fMRI, CT, or PET scanning.

[ ]  **Ingestion of food stuffs or drugs?**

This refers to the consumption of any substance which may impact on psychological or physical state. Substances may include but are not limited to food, beverages or drugs.

[ ]  **Physical testing?**

This refers to any test in which a participant must perform an action resulting in the use of any muscle of the body and/or involves the use of scanning procedures, eye-trackers, mounted body cameras, sensors or electrodes, or the taking of swabs from any cavity of the body, respiratory challenge testing or recording of peak flows, EEG, ECG, Exercise ECG, Treadmill work.

[ ]  **Psychological intervention?**

This refers to any test which purposely alters the mood of the participant or involves administering personality inventories, or any other form of psychological test.

***OR***

[ ]  **I confirm that my research does not fall into any of the above categories *(please***

 ***go straight to Part 3)***

**Part 2: Clinical Trials Insurance**

**Please complete this section only if you ticked one of the boxes in Part 1**.

Does your research study involve:

[ ]  **Pregnant persons as participants with** **procedures other than blood samples**

 **being taken from them?**

[ ]  **Children aged five or under with procedures other than blood samples**

 **being taken from them?**

[ ]  **Activities being undertaken by the lead investigator or any other member of**

**the study team in a country outside of Ireland? *If ‘Yes’, please refer to the ‘Travel Insurance’ guidance on Page 1 of this form.***

***OR***

[ ]  **I confirm that my research does not fall into any of the above categories**

**Part 3: Other Hazards**

Does your research study involve:

[ ]  **Working with Hepatitis, Human T-Cell Lymphotropic Virus Type iii (HTLV iii), or**

**Lymphadenopathy Associated Virus (LAV) or the mutants, derivatives or variations thereof or Acquired Immune Deficiency Syndrome (AIDS) or any syndrome or condition of a similar kind?**

[ ]  **Working with Transmissible Spongiform Encephalopathy (TSE), Creutzfeldt-Jakob**

**Disease (CJD), variant Creutzfeldt-Jakob Disease (vCJD) or new variant Creutzfeldt-Jakob Disease (nvCJD)?**

[ ]  **Working in hazardous areas or high risk countries? *Please refer to the ‘High Risk***

 ***Countries’ guidance in this Section.***

[ ]  **Working with hazardous substances outside of a controlled environment?**

[ ]  **Working with persons with a history of violence, substance abuse or a criminal**

 **record?**

***OR***

[ ]  **I confirm that my research does not fall into any of the above categories**

SECTION 9 Confidentiality

*(Review TUS Data Protection Policy for this section)*

**49. Explain what measures will be taken to ensure confidentiality of the data collected**

|  |
| --- |
|  |

**50. Confirm one copy the study data be held on TUS One Drive and encrypted.**

 YES: [ ]  NO: [ ]

If NO, please give reasons

|  |
| --- |
|  |

**51. Confirm only the research team and Research supervisor will have access to the data**

 YES: [ ]  NO: [ ]

If NO, please give reasons

|  |
| --- |
|  |

**52. Confirm the data be held so that participants cannot be identified from computer files (i.e. no name, address, medical chart number or other potential identifier such as GMS or RSI number.**

 YES: [ ]  NO: [ ]

If NO, please give reasons

|  |
| --- |
|  |

**53. Explain how long Data will be held and why this duration is needed.**

|  |
| --- |
|  |

**54. Will the study include the use of any of the following?**

Audio/Video recordings YES: [ ]  NO: [ ]

Observation of participants: YES: [ ]  NO: [ ]

**If YES to either:**

1. How are confidentiality and anonymity to be ensured?

|  |
| --- |
|  |

(ii) What arrangements have been made to obtain consent for these procedures?

|  |
| --- |
|  |

(iii) Confirm the recording will be transferred to TUS One Drive as soon as possible.

 YES: [ ]  NO: [ ]

If NO, please give reasons

|  |
| --- |
|  |

**55. Will the participants’ medical records be examined by investigators in the study?**

 YES: [ ]  NO: [ ]

If YES, will information relevant **only** to this study be extracted: YES: [ ]  NO: [ ]  Not applicable: [ ]

(i) If extra information is extracted, please justify

|  |
| --- |
|  |

(ii) What, if any, additional steps have been taken to safeguard the confidentiality of personal medical records?

|  |
| --- |
|  |

**56. Will research workers outside the employment of TUS examine medical or other personal records?**

 YES: [ ]  NO: [ ]

If YES, it is the responsibility of the Principal Investigator to ensure that research workers understand that:

Information obtained about and from research participants is confidential to the study and must not be divulged except in legitimate methods of study data presentation or exceptional circumstances as discussed and agreed with the principal investigator.

SECTION 10 Sign Off

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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Researcher’s Signature: Date:** Click or tap to enter a date.

 **Print Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Supervisor’s Signature: Date:** Click or tap to enter a date.

 **Print Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Please ensure that you complete the checklist on the front cover of this application form and include all relevant enclosures.**

**THANK YOU.**

ANNEX 1 - New medical product or medical device

*This form is to be used if the study involves the use of a new medical product or medical device, or the use of an existing product outside the terms of its product license.*

**(i) Does this project have HPRA approval or has an application been made?**

YES: [ ]  NO: [ ]  Not applicable: [ ]  Application is at present with IMB: [ ]

If approval applied for, state date of application: Click or tap to enter a date.

(ii) Is a pharmaceutical or commercial company arranging this trial?

YES: [ ]  NO: [ ]

If YES, attach indemnification.

If NO, has the licensing authority been notified? YES: [ ]  NO: [ ]

(iii) Does the drug(s) or medical device have a product license(s) for the purpose for which it is to be used?

YES: [ ]  NO: [ ]

If YES, please give details

|  |
| --- |
|  |

(iv) Is any drug or medical device being supplied by a company with a Clinical Trial Exemption Certificate or in response to an investigator with a Clinical Trial Exemption, or Doctors’ Exemption?

YES: [ ]  NO: [ ]

If YES, give details of:

|  |  |
| --- | --- |
| Clinical Trial Certificate Number: |  |
| Clinical Trial Exemption Number: |  |
| Doctors’ Exemption Number: |  |

(v) Details of drug use or medical device *(please complete the table below)*

|  |  |
| --- | --- |
| Approved Name: |  |
| Generic Name: |  |
| Trade Name: |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Strength** | **Dosage** | **Frequency** | **Route** | **Duration of course** |
|  |  |  |  |  |
|  |  |  |  |  |

**(vii) Who will administer the drug or fit the medical device?**

|  |
| --- |
|  |

(viii) If a medical device, has the device been through acceptance and safety testing?

 YES: [ ]  NO: [ ]

Please give details

|  |
| --- |
|  |

(ix) Who is supplying the drug(s)/medical device? (If imported, name country)

|  |
| --- |
|  |

(x) Who will dispense the drug(s)/medical device?

|  |
| --- |
|  |

**What is their qualification to dispense the drug(s)/medical device?**

|  |
| --- |
|  |

(xi) Does the organisation and performance of this trial conform to European Directives on Good Clinical Practice?

 YES: [ ]  NO: [ ]

If no, please detail and explain

|  |
| --- |
|  |

ANNEX 2 - se of ionizing or non-ionising radiation

*This form is to be used if the study involves 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.*

1. **RADIOACTIVE SUBSTANCES**

**(i) Details of substances to be administered** *(please complete the table below)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Investigation** | **Radionucleide** | **Chemical form** | **Quantity of radioactivity to be administered (MBq)** | **Route** | **Frequency** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

**(ii) Estimated Effective Dose (Effective Dose Equivalent) (mSv)**

 (Please supply source of reference or attach calculation)

|  |
| --- |
|  |

**(iii) Absorbed dose to organ or tissues concentrating radioactivity (mGy) (Specify dose and organ)**

 (Please supply source of reference or attach calculation)

|  |
| --- |
|  |

**(iv) Administration of Radioactive Substances Advisory Committee certificate holder to oversee/administer substance**

|  |  |
| --- | --- |
| **Name of Person:**  |  |
| **Position:**  |  |
| **Certificate No.:**  |  |

*I have assisted in and approve the protocol and arrangements that have been made in this project for the administration of the radioactive substance(s).*

Signature: Date: Click or tap to enter a date.

1. **X-RAYS**

**(i) Details of radiographic procedures** *(please complete the table below)*

|  |  |  |
| --- | --- | --- |
| **Investigation** | **Organs** | **Frequency** |
|  |  |  |
|  |  |  |
|  |  |  |

**(ii) Estimated Effective Dose (Effective Dose Equivalent) (mSv)**

 (Please supply source of reference or attach calculation)

|  |
| --- |
|  |

1. **NON IONISING RADIATION**

**(i) Details of procedures** *(please complete the table below)*

|  |  |  |
| --- | --- | --- |
| **Investigation** | **Organs** | **Frequency** |
|  |  |  |
|  |  |  |
|  |  |  |

**(ii) Who has given safety advice?**

|  |  |
| --- | --- |
| Name of Person: |  |
| Position:  |  |
| Qualification of advise:  |  |

*I have assisted in and approve the safety of the protocol and arrangements that have been made in this project*

**Signature**: **Date**: Click or tap to enter a date.

ANNEX 3 - Risk Assessment Form

**Risk Assessment Form – Procedures Involving Human Subjects**

|  |  |
| --- | --- |
| **Procedure no.**: |  |
| **Title of Procedure:**  |  |
| Name of Assessor(s):  |  |
| Assessment Date:  |  |
| Does this procedure already have ethical approval?  | YES: [ ]  NO: [ ]  |
| If YES, enter Approval No. and Expiry Date: |  |
| Approval No: |  |
| Expiry Date: | Click or tap to enter a date. |

**1. Please provide a brief description of the procedure;**

|  |
| --- |
|  |

**2. Location in which the Procedure will take place**

(e.g. Research Laboratory – Room No. , Teaching Laboratory – Room No., Hospital clinic – specify, etc)

|  |
| --- |
|  |

**3. Subject(s) to be used** (tick as appropriate)

|  |
| --- |
| Undergraduate student(s) |[ ]
| Postgraduate student(s) |[ ]
| University staff or campus personnel |[ ]
| Members of the general public  |[ ]

**4. What is the level of any potential risks for participants?**

**[To be explained BEFORE obtaining consent]**

|  |
| --- |
| None |[ ]
| Minimal only |[ ]
| Moderate |[ ]
| Significant |[ ]

(ii) If the risk is other than minimal, please give details and likelihood of risk occurrence

|  |
| --- |
|  |

(ii) If the risk is other than minimal, please give details of precautions taken to minimise the risk

|  |
| --- |
|  |

5. Actions to be taken in the event of adverse response or medical emergency

Please provide details of arrangements to deal with adverse events, including reporting to the relevant authorities and follow-up

|  |
| --- |
|  |

6. Appropriate level of supervision required for procedure (please tick as appropriate)

|  |
| --- |
| Post-graduate researcher |[ ]
| Research/ lecturing Staff |[ ]
| Paramedical personnel |[ ]
| Medical personnel – Nurse |[ ]
| Medical personnel – Doctor |[ ]
| Medical personnel – Other |[ ]

If other personnel, please specify title and/or required qualification

|  |
| --- |
|  |

**7. Other documentation required for this assessment**

|  |
| --- |
| Pre-test subject questionnaire |[ ]
| Detailed protocol |[ ]
| Other |[ ]

If other documentation is required, please describe

|  |
| --- |
|  |

**8. Signature**

**Signed**: **Date:** Click or tap to enter a date.

 Signature of Principal Investigator

ANNEX 4

|  |  |
| --- | --- |
| **Consent Form for** | **xxxxxxxx** |

|  |  |  |
| --- | --- | --- |
| I,  | xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx | have agreed to take part in the above research project. |
|   |  |  |

Yes [x]  No [ ]

•I understand that I will take part in a xxxx minute interview with xxxxx about my experiences of the xxxxxx. The interview will be audio recorded if held in person or will be recorded on Zoom/MS Teams if held virtually.

Yes [ ]  No [ ]

•My participation is fully voluntary. Yes [ ]  No [ ]

•I understand that I have the right to withdraw from this process at any time during the interview or up to two weeks after the interview is finished. Yes [ ]  No [ ]

•If I withdraw from the study there will be no negative consequences. Yes [ ]  No [ ]

•I am aware I can view all research and transcripts that have taken place concerning my involvement. I can request a copy of the out come from the researcher. Yes [ ]  No [ ]

•All information will be confidential and used only for this study.

•I understand that a pseudonym (alternative name) I select will be used to protect my anonymity and confidentiality and that any information that might identify me will be changed. Yes [ ]  No [ ]

•I agree that quotations from my interview may be used for the purpose of the research. I would like the name used for direct quotations from me to be \_\_(select own or from list)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

**Signed**: **Date** Click or tap to enter a date.

***FOR COMPLETION BY HEAD OF FACULTY/SCHOOL/DEPARTMENT***

**Risk Assessment Form – procedures involving human subjects**

|  |  |
| --- | --- |
| **In the Faculty / Department / Institute/ Centre of*:***  |  |
| **Procedure no.**: |  |
| **Title of Procedure:**  |  |
| Name of Assessor(s):  |  |
| Assessment Date:  |  |

**9. Approval of Procedure**

[ ]  Granted

[ ]  Subject to conditions (see below)

[ ] Refer to Hospital Ethics Committee

 Other, please specify

|  |
| --- |
|  |

**10. Comments and/or conditions**

|  |
| --- |
|  |

**11. Signature**

**Signed**: **Date:** Click or tap to enter a date.

 Signature of Head of Faculty/School/ Department/Centre

***(Please copy this Annex as necessary)***

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**

1. A succinct background to be provided and to include reference to published work [↑](#footnote-ref-1)
2. Please append detailed study protocol to this application; this brief description summarizes protocol only. [↑](#footnote-ref-2)
3. *If you are in possession of any referee or other scientific critique reports relevant to your proposed research, please forward copies with your application form.* [↑](#footnote-ref-3)
4. *\* Please see Guidance Notes* [↑](#footnote-ref-4)