



UNIVERSITY of LIMERICK
OLLSCOIL LUIMNIGH

For Office Use Only: S&EREC No: .

**Faculty of Science & Engineering Research Ethics Committee
Full Application Form**

Form must be Typed

[If your research involves Hospital or GP patients (or HSE members of staff) recruited in medical facility then you will need to apply to the local HSE ethics committee not the FREC].

1 Title of Research Project

2 Period for which approval is sought (insert an End Date only)
Start Date: Date of Approval End Date:

3 Project Investigators

3a Principal Investigator (Supervisor)	
Name	
Department	
Position	
Qualifications	
Telephone Number	
e-mail address	

3b Other Investigators (Student)		
Name	Qualifications & Affiliation	Signature

4 Head of Department(s)

I have read through this application and am aware of the possible risks to participants involved in this study. I hereby authorise the Principal Investigator named above to conduct this research project.

Name	Department	Date	Signature

5 Study Descriptors

Please indicate the terms that apply to this research project

Healthy Adults	<input type="checkbox"/>	Healthy Children (< 18 yrs)	<input type="checkbox"/>
Patient Adults	<input type="checkbox"/>	Patient Children (< 18 yrs)	<input type="checkbox"/>
'Potentially Vulnerable' Adults	<input type="checkbox"/>	'Potentially Vulnerable' Children	<input type="checkbox"/>
Physical Activity	<input type="checkbox"/>	Questionnaire/Interview	<input type="checkbox"/>
Medical Devices / Drugs	<input type="checkbox"/>	Video Recording/Photography	<input type="checkbox"/>
Food/Drink Supplementation	<input type="checkbox"/>	Collection of Personal Details	<input type="checkbox"/>
Measure Physical in Nature	<input type="checkbox"/>	Measure Psychological in Nature	<input type="checkbox"/>
Body Tissue Samples	<input type="checkbox"/>	Observational	<input type="checkbox"/>
Body Fluids Samples (e.g. blood)	<input type="checkbox"/>	Record Based	<input type="checkbox"/>

6 Project Design

6a Justification for Research Project *(Include reference to published work)*

6b Hypotheses or questions to be answered

6c Plan of Investigation

6d Will the participants be recorded? Yes No

If Yes will the recordings be Video Audio

Why is recording required?

6e Will a prototype be developed? Yes No

If Yes what format will this prototype take?

6f Research procedures

6g Associated risks to subjects

6h Statistical approach to be used and source of any statistical advice

6i Location(s) of Project

7 Subjects

7a How will potential research participants be sourced and identified?

7b Will research participants be recruited via advertisement (poster, e-mail, letter)?

YES NO

If YES, please provide details below, or attach the recruitment advertisement if written.

7c How many participants will be recruited?

Male Female

Provide further information if necessary

7d What are the principal inclusion criteria? *(Please justify)*

7e What are the principal exclusion criteria? *(Please justify)*

7f What is the expected duration of participation for each participant?

7g What is the potential for pain, discomfort, embarrassment, changes to lifestyle for the research participants?

7h What arrangements have been made for participants who might not adequately understand verbal explanations or written information in English?

7i Have arrangements been made to accommodate individuals who do not wish to participate in the research? **(NB This mainly relates to research taking place in a classroom setting)**

Yes No N/A

If Yes
Please state what these arrangements are:

7j Will subjects receive any payments or incentives, or reimbursement of expenses for taking part in this research project?

YES NO

If YES, please provide details below, and indicate source of funding:

8 Confidentiality of collected data

8a What measures will be put in place to ensure confidentiality of collected data?

8b Where will data be stored, ie Room Number?

8c Who will have custody and access to the data?

8d Data must be stored for 7 years after publication: How do you propose to store the information once the project is completed? Will the file/computer be password protected? (Information must not be stored on student's PC or on a USB Key)

Where will the information be stored (room number):

9 Drugs or Medical Devices

Are Drugs or Medical Devices to be used?

YES NO

If YES please complete 9a to 9c

9a	Details of the Drugs or Devices (including name, strength, dosage, route of administration)
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9b	Details of Clinical Trial Certificate, Exemption Certificate or Product Licence (The Product Licence must cover the proposed use in the Project)
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9c	Details of any Risks (Both to subjects and staff; indicate current experience with the drug or device)
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10 Insurance Cover

<p>Insurance cover is required for all research carried out by UL employees. Principal Investigators/Supervisors should carefully view the University's 'Guidelines on Insurance Cover for Research' document and the University's Insurance cover to ascertain if their proposed research is covered. These documents are available at www.ul.ie/insurance.</p> <p>Where any query arises about whether or not proposed research is covered by insurance, the Principal Investigator/Supervisor must contact the University's Insurance Administrator at cliona.donnellan@ul.ie to confirm that the required level of insurance cover is in place.</p> <p>Please indicate by way of signature that the research project is covered by UL's insurance policies:</p> <p>PI/Supervisor signature: _____</p>

11 Information Documents

Please note: failure to provide the necessary documentation will delay the consideration of the application. Please complete the checklist below:

<i>Documents</i>	<i>Included?</i>		
Participant Information Sheet	YES	<input type="checkbox"/>	N/A
Participant Consent Form	YES	<input type="checkbox"/>	N/A
Parent/Guardian Information Sheet	YES	<input type="checkbox"/>	N/A
Parent/Guardian Consent Form	YES	<input type="checkbox"/>	N/A
School Principal Information Sheet	YES	<input type="checkbox"/>	N/A
School Principal Consent Form	YES	<input type="checkbox"/>	N/A
Teacher Information Sheet	YES	<input type="checkbox"/>	N/A
Teacher Consent Form	YES	<input type="checkbox"/>	N/A
Questionnaire/Interview/Survey Questions	YES	<input type="checkbox"/>	N/A
Recruitment Letters/Advertisements/Emails etc.	YES	<input type="checkbox"/>	N/A
Acceptance of UL Child Protection Form	YES	<input type="checkbox"/>	N/A

*Please ensure any additional documents are included with this application.
These should be attached as a single document and included in the e-mail submission.*

12 Declaration

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

I undertake to abide by the ethical principles outlined in the Science & Engineering Research Ethics Committee guidelines.

If the research project is approved, I undertake to adhere to the study protocol without unagreed deviation, and to comply with any conditions sent out in the letter sent by the Science & Engineering Research Ethics Committee notifying me of this.

I undertake to inform the Science & Engineering Research Ethics Committee of any changes in the protocol, and to submit a Report Form upon completion of the research project.

Name of Principal Investigator
Signature of Principal Investigator (or Head of Department*)
Date

**Please note: where the Principal Investigator is not a permanent employee of the University of Limerick, the relevant Head of Department should sign this declaration.*

1. Once completed, the complete application with supporting documentation should be submitted **electronically in pdf format** to eileen.madden@ul.ie
2. In addition, **1 copy** of the fully signed application and any attachments should be submitted to:
The Secretary,
Faculty of Science & Engineering Research Ethics Committee,
University of Limerick
3. **This form must be submitted and approval granted before the study begins.**

S&EREC No. _____



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INFORMATION SHEET

Dear ??

My name is ???? and I am currently undertaking a ??? at the University of Limerick under the supervision of ?????. The title of my proposed research is ??? The purpose of this project is to ???? (Give a brief description and method – interview/group discussion etc. The description should briefly explain what a participant will be expected to do, arrangements for confidentiality, how the information collected will be used)

(Participants should be informed of any risks involved in the study. The length of time required for their participation, their right to not participate or withdraw at any time. Participants should also be informed if they are to be audio/video recorded.)

[The following must be included in all Information Sheets]

If you have further questions regarding this research please feel free to get in touch with either myself or my supervisor using the email addresses listed below.

If you have concerns about this study and wish to contact someone independent, you may contact: The Chair, Faculty of Science & Engineering Research Ethics Committee, University of Limerick, Limerick. Tel: 061 213471

Yours sincerely,

Student Name, Email Address. (UL email only, no mobile number)	Supervisor Name, Department, Telephone Number and Email Address
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CONSENT FORM

Consent Section:

I, the undersigned, declare that I am willing to take part in research for the project entitled “**Insert Name of Research Project**”.

- I declare that I have been fully briefed on the nature of this study and my role in it and have been given the opportunity to ask questions before agreeing to participate.
- The nature of my participation has been explained to me and I have full knowledge of how the information collected will be used.
- I am also aware that my participation in this study may be recorded (video/audio) and I agree to this. However, should I feel uncomfortable at any time I can request that the recording equipment be switched off. The recordings will be destroyed once they have been transcribed. **(Remove this bullet point if participation is not being recorded)**
- I fully understand that there is no obligation on me to participate in this study
- I fully understand that I am free to withdraw my participation at any time without having to explain or give a reason
- I am also entitled to full confidentiality in terms of my participation and personal details

Signature of participant

Date

In all cases involving research on participants under the age of 18, the Child Protection Form must be signed by all researchers involved in the project and submitted with the application.

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Acceptance of the University of Limerick Child Protection Guidelines

I have read the University of Limerick Child Protection Guidelines and agree to abide by its contents. There is no reason why I would be considered unsuitable to work with children or young people.

Signature of Principal Investigator: _____ Date: _____

Student Signature: _____ Date: _____