Faculty of Education and Health Sciences Research Ethics Committee

Research Ethics Application Form

Title of Research Project:

IF RESUBMISSION PLEASE QUOTE REFERENCE NO:

IF MINOR CHANGES TO PREVIOUSLY APPROVED APPLICATION (I.E. CHAIR'S ACTION) PLEASE REFER TO PAGE 2 - SECTION 1

Period for which approval is sought:

From: ☐ Use the Date of Approval

Until:

Primarily Faculty	Primarily UG Student	Primarily PG Student	Shared
☐	☐	☐	☐

Principal Investigator Details:	
Name:	
Department:	
Position:	
Qualifications:	
Telephone Number:	
Email Address:	

Other Investigators:		
Name	**Position and Affiliation**	**Signature**

Head of Department(s) Approval:	
I have read through the application and I am aware of the possible risks to participants in this study. I hereby authorise the Principal Investigator and other investigators named above to conduct this research project.	
Name:	
Department:	
Date:	
Signature:	

Section 1: Eligibility for Chair's Action

Has research of a similar nature previously received approval from EHSREC ("Similar" is defined as follows: distinctions only in the researchers involved, differences in the number of subjects involved, small alterations to the procedures being used, and change in the location of the research). If so you can apply for Chair's Action to your previously approved application. See here for more information. If deemed necessary the Chair may request a full Research Ethics application.

Please note that from 1st January 2013 EHSREC no longer reviews Chair's Action applications which refer to applications previously reviewed by any other UL Ethics Committee other than EHSREC. A full application will be required.

Please refer to Guide for Submitting Applications to EHS Research Ethics Committee when completing this form

Section 2: Ethical Issues

1. Does this application involve research with:

a. People under the age of 18? Read more	◯ Yes	◯ No
b. People with diagnosed psychological impairments?	◯ Yes	◯ No
c. People with a diagnosed learning difficulty?	◯ Yes	◯ No
d. People dependant on the protection/under the control/influence of others (e.g. people in care, prisoners, students with whom the researcher has a supervisory relationship, etc.)?	◯ Yes	◯ No
e. Relatives of sick people (e.g. parents of sick children)?	◯ Yes	◯ No
f. People who may have only a basic knowledge of English?	◯ Yes	◯ No
g. Other populations that are potentially vulnerable?	◯ Yes	◯ No

If 'YES' to (g) please describe:

2. Does this application deal with:

a. Sensitive personal issues? (e.g. suicide, bereavement, gender identity, sexuality, fertility, abortion, gambling, illegal activities, illicit drug taking, substance abuse engaging in criminal behaviour?	◯ Yes	◯ No
b. Any act that might diminish self-respect or cause shame, embarrassment or regret?	◯ Yes	◯ No
c. Research into politically and/or racially/ethically and/or commercially sensitive areas?	◯ Yes	◯ No
d. Issues which might otherwise give rise to a risk of loss of employment, for the participant?	◯ Yes	◯ No
e. Other issues that may be considered sensitive?	◯ Yes	◯ No

If 'YES' to (e) please describe:

3. Does the proposed research procedures involve:

a. Use of personal records without consent?	◯ Yes	◯ No
b. Deception of participants or use of placebos?	◯ Yes	◯ No
c. The offer of large inducements to participate?	◯ Yes	◯ No
d. Audio or visual recording without consent?	◯ Yes	◯ No
e. Invasive physical interventions or treatments?	◯ Yes	◯ No
f. Research that might put researchers or participants at substantial risk?	◯ Yes	◯ No
g. Storage of results or data for less than 7 years?	◯ Yes	◯ No
h. Dealing with topics, using methodologies, or reporting of findings in a way that is likely to cause pain, discomfort, embarrassment, or changes to lifestyle for participants?	◯ Yes	◯ No
i. Other procedures that may be considered invasive?	◯ Yes	◯ No

If 'YES' to (i) please describe:

Section 3: Approved Procedures

If the answer to any of the questions in Section 2 is **Yes,** you must complete this section.

Does the research follow any **UL/EHSREC Approved Procedures** in relation to this sensitivity or intrusion? **If so, please attach a copy of this procedure to your application.** ◯ Yes ◯ No

Procedure Name(s) and Approval Number(s)

Section 4: Study Design and Conduct of the Study

a. What are the aims of this research?

b. Include a short justification for choosing this research study

c. Provide a description of the study, clearly outlining what is required of all participants. Describe the study using the following headings; Brief background to project, Study design, Participants, Procedures/Methods, Data Collection and analytical approach. Further details provided in Guide for Submitting Application to EHSREC.

Include the name and number of any University of Limerick approved Risk Assessment Procedure.

c. Continued - Only use if necessary

Section 5: Recruitment of Research Participants

a. Describe the population you will recruit from, including their gender, age range and ethnicity (if ethnicity is relevant). Provide information on any additional specific inclusion or exclusion criteria.

b. How will you source or identify your participants?*

**If you plan to recruit via a letter, email or a poster, a copy of this must be submitted to the committee with this application.*

c. How many participants will you recruit? (the number should be the maximum that you will recruit, allowing for drop-outs and other losses). Please provide justification for this number, if applicable.

Number of Participants:

d. Provide details of any financial remuneration or any other form of reward which the participants will receive.

e. Where will the research work be done?

- ◯ UL
- ◯ External Location
- ◯ Combined UL\External

If External or Combined location please provide details:

Section 6: Consent

See here for more information.

- Remember that you must **submit** a participant **informed consent form** and **information sheet** with this application; *or provide other evidence of how consent will be obtained where these are not possible (e.g. in telephone interviews*). When using anonymous questionnaires/surveys please note that implied consent is sufficient.
- In the case of children (under 18) and adults who are unable to give consent, please explain how consent will be obtained and provide the documentation to be used to obtain parent or guardian consent.
- If your participants can't read or speak English (or Irish, if your research is aimed at Irish speakers), explain how you will obtain consent.
- In situations where obtaining free consent may be difficult (e.g. in prisons), explain how you will ensure that free consent is given.

For research in schools, please provide a copy of the cover letter to the school principal

Details of how you will obtain consent (where relevant):

Section 7: Care and Protection of Research Participants

a. What is the total participation time for each participant (in hours /minutes)?

Participant Group	Hours	Minutes

b. If there is multiple testing sessions for each participant, please provide a breakdown detailing how the total participation time is divided over the course of the experiment or research study.

c. Provide detailed information on any potential risks to the participant or researcher from procedures or techniques to be employed in this research. Where a substantive risk is identified, provide detail on steps that have been taken to minimise this risk. Note that risk is defined by the committee as the potential to cause short or long term discomfort, pain, physical injury or emotional distress that is greater than that which would be experienced in the participant's everyday life.

d. Explain what the potential benefits of the study are. Explain why these potential benefits of the study justify any risks to participants (as outlined above) and participant time input (as described in section 7a). If predictable risks are identified please state how these risks are balanced against anticipated benefits.

Section 8: Protection of Participant Confidentiality

a. Who will have access to the data collected from participants?

b. How will confidentiality be ensured? (outline the steps taken to ensure data security in collecting and storing information). Read more

c. How long will the data be kept? How will data be destroyed at the end of the storage period? (Note that you are obliged to store the data for between 7 and 10 years, and ensure that it is effectively destroyed at the end of this period)

Duration of data storage (years):	
Date of destruction:	
Destruction method:	

Section 9: Feedback to Participants and Relevant Communities

Describe how the results of the research will be made available to the participants and to any community group that the research findings would be relevant to.

Section 10: Indemnity

If your planned research methodology is substantially different to that which you have obtained ethical approval for before at UL, and has identifiable potential risks to participants or experimenters you should contact Cliona Donnellan (cliona.donnellan@ul.ie) to confirm that the research project will be insured. You should also contact Cliona if the planned work requires invasive procedures. This may involve contacting the insurers, so allow several days for this process if it is required.

Note that UL's current insurance does not cover clinical trials.

This research project will be covered by UL's indemnity policy: ◯ Yes ◯ No

Section 11: Document Checklist

Which documents are attached? Please tick N/A if appropriate:

Volunteer information sheet	◯ Yes	◯ N/A
Parent / carer information sheet	◯ Yes	◯ N/A
Volunteer informed consent form	◯ Yes	◯ N/A
Parent / carer informed consent form	◯ Yes	◯ N/A
Letter to school principal	◯ Yes	◯ N/A
Questionnaire	◯ Yes	◯ N/A
Interview / survey questions / focus group script	◯ Yes	◯ N/A
Recruitment letter / email / poster	◯ Yes	◯ N/A
Acceptance of UL child protection form (signed by all researchers)	◯ Yes	◯ N/A
EHSREC or PESSREC Procedures	◯ Yes	◯ N/A

Section 12: Declaration

To be completed by the Principal Investigator:

The information in this application form is accurate to the best of my knowledge. I undertake to abide by the ethical principals outlined by UL ethics policy. If this proposal is approved by the Ethics Committee, I undertake to adhere to the study protocol without unagreed deviation and to comply with any conditions required by the ethics committee.

I undertake to inform the UL research ethics committee of any changes in the protocol, and to submit a Report Form upon completion of the research project.

Please note that it is the responsibility of the Principal Investigator to ensure that all documentation is complete and this documentation should be submitted by the Principal Investigator (both electronic and hard copy) to the EHS Ethics administrator.

Is this application complete with:

a. All required documentation, including consent forms, information sheets and research instruments (or where some documentation is not included is there an explanation as to why)	◯ Yes	◯ No
b. All required signatures	◯ Yes	◯ No

If you have answered 'No' to any of the above questions the application is incomplete and will be returned without consideration by the committee.

Name of Principal Investigator: _____

Signature of Principal Investigator: _____

Date: _____

Section 13: Appendices

All Appendices (e.g. *Information Sheets, Informed Consent Forms, Recruitment Documents (Email/Poster), Data Collection Tools, Interview Protocols)* should be referred to in the main application form. Applicants must create a single electronic document to include all appendices. Multiple files will not be accepted. Please note appendices should only contain the above mentioned documents and should not be used as continuation sheets.

Include space to insert EHSREC approval number on all recruitment information and consent forms once ethical approval is received.