Faculty of Education and Health Sciences

Research Ethics Committee Research Ethics Application Form

Please consult the accompanying Guidance Notes for more information about how to complete this form. Provide an answer in every section of this form. Do not leave any answer field blank. Enter N/A if you think the question does not apply to your project. See the EHS REC Guidance Notes for advice about how to complete this form.

Project Title:

IF RESUBMISSION, Enter EHS REC number here:

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/School:	
Position:	
Qualifications:	
Telephone /Mobile contact number:	
Email Address:	

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

Head of Department(s) Approval:	
I have read the application and acknowledge that the named PI is an employee in UL working in the named department within the EHS faculty.	
Name:	
Department/School:	Select One
Date:	
Signature:	

Continue to next page.

Research Ethics Application Form

Section I: Ethical Issues Checklist

Use this checklist to identify any aspects of your proposed research that could pose greater than minimal risk to your participants:

A. Population. Is there greater than minimal risk associated with participation in your study for the population(s) you plan to sample? Will you recruit participants who may have limited capacity to give voluntary informed consent? Will you recruit participants because of their membership in a particular group?

	No	Yes
1. Participants younger than 18 years old.	☐	☐
2. Participants dependent on the protection/under the control/influence of others (e.g., people in care; prisoners; people like students or patients with whom the researcher has a dual relationship)	☐	☐
3. Participants with only a basic knowledge of English.	☐	☐
4. People with significant physical or mental health problems.	☐	☐
5. People with a diagnosed learning difficulty.	☐	☐
6. Relatives of sick people (e.g., parents of sick children).	☐	☐
7. Another population or group who are potentially vulnerable.	☐	☐

B.Topic: Does the topic you plan to investigate involve greater than minimal risk to your participants, more than they would experience in everyday life?

1. Sensitive personal issues? (e.g., suicide, bereavement, gender identity, sexuality, fertility, abortion, gambling, illegal activities, illicit drug or substance abuse engaging in criminal behaviour).	☐	☐
2. Any acts that might diminish self-respect or cause shame, embarrassment, or regret.	☐	☐
3. Research into politically and/or racially/ethically and/or commercially sensitive areas.	☐	☐
4. Issues that might otherwise give rise to a risk of loss of employment, for the participant.	☐	☐
5. Any other sensitive topic that may pose greater than minimal riskto participants.	☐	☐

C. Procedures: Do the procedures you plan to use pose greater than minimal risk?

1. Use of personal records without consent.	☐	☐
2. Deception or use of placebos.	☐	☐
3. The offer of large inducements to participate.	☐	☐
4. Audio or visual recording without consent.	☐	☐
5. Invasive physical interventions or treatments.	☐	☐
6. Research that might put researchers or participants at substantial risk.	☐	☐

D. Any other procedures that would be considered invasive or likely to cause pain, discomfort, embarrassment, or changes to lifestyle for participants. ☐ ☐

Continue to next page.

If you answered 'yes' to any of the items in the checklist on page 2, describe and explain the risk to participants or researchers and ensure that your answers in the rest of the application explain how your procedures address the identified risk(s). Enter N/A for not applicable if you have not answered yes to any items in the checklist.

Section II Approved Procedures, Risk Assessments, Child Protection/Safeguarding & DPIA

A. Will you use any EHSREC or PESSREC Approved Procedures in your data collection activities?

No Yes **Click Here to Access the EHSREC and PESS REC Approved Procedures**

If yes please note the approved procedure in the text box below and include reference to it in Section III.

Procedure Name(s) and Approval Number(s)

B. Will you collect data from any participants who are minors (under 18 years old)? No Yes

If yes, every named researcher must sign a Child Protection Guidance document and all signed forms must be included in your Appendix of Study Materials.

C. According to the Health Research Regulations, health research is defined as:

- Research with the goal of understanding normal and abnormal functioning, at the molecular, cellular, organ system and whole-body levels;
- Research that is specifically concerned with innovative strategies, devices, products or services for the diagnosis, treatment or prevention of human disease or injury;
- Research with the goal of 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 with the goal of improving the efficiency and effectiveness of health professionals and the health care system;
- Research with the goal of 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.
- Health research referred to in clause (i) to (v) above may include action taken to establish whether an individual may be suitable for inclusion in the research.

Does your research match one or more of these categories of health research? No Yes

If Yes, the PI should complete a Screening Questionnaire to assess whether the research will involve material risks to an individual's privacy. Where indicated by the responses to the Screening Questionnaire, a full DPIA should be completed. You can find all relevant guidance and documentation here. (DPIA: Data Protection Impact Assessment).

If your answer is Yes, you may submit your EHS REC proposal while your DPIA screening is underway. However, final ethical approval will not be granted until you submit the outcome of your Screening Questionnaire and full DPIA when indicated, to the EHS REC. The DPIA documentation should be included in your appendix of study materials.

Continue to next page.

Section III: Aims, Objectives, and Research Questions

A. Clearly and succinctly, without jargon or technical language, state your research questions, hypotheses, and aims for your research project. Your aims are your intentions and desired outcomes of the project.

B. Provide a full description of the proposed project so that the reviewers can understand what you are doing, why you are doing it, and with whom. Use these headings to organize the information you provide in this section: a) background and rationale; b) study Design; c) Procedures/Methods (population to be sampled, recruitment procedures, consenting procedures, data collection procedures, any PESS/EHS REC Approved Procedures); d) Data Management, Protection, and Confidentiality (collecting, recording, storing, and processing of personal data); e) Plan for Analysis. You will be asked to elaborate on some of these answers in subsequent sections, so please be brief here. *Remember to see guidance notes for further information.*

Continue to next page.

Continue Section IIIB here as needed.

Continue to next page.

Section IV: Recruitment of Research Participants

A. Describe the population you intend to sample in terms of their relevant demographic characteristics (e.g., age, gender, nationality, race/ethnicity) and any other bases for inclusion or exclusion (e.g., student, patient, athlete, coach, teacher, practitioner). Explain your inclusion and exclusion criteria.

B. Describe your recruitment procedures. How will participants learn about your study? Note whether you will work with a gatekeeper and/or need permission from the gatekeeper to recruit participants (e.g., from an organization or school). Include texts and images to be used in all recruitment materials (e.g., emails, social media announcements, letters to gatekeepers, and so forth, in your appendix of study materials).

C. What is your target sample size? This should be the maximum number, accounting for attrition. Please explain how you arrived at this target sample size (e.g., power analysis, accepted discipline practice or other basis).

Continue to next page.

D. Will you offer your participants any remuneration for participation? Explain here and include explanation of disciplinary practices/norms where relevant. If the proposed remuneration is substantial relevant to your discipline's practices, please justify.

E. Where will you collect data from your participants (check all that apply)?

☐ Online/Remote ☐ On campus location ☐ External location off campus

Please explain your answer here:

Section V: Consent

You must submit all consenting materials for all participant groups in your appendix of study materials. Depending on your study design, these will include: a) information sheet(s), b) consent form(s), c) Research Privacy Notice(s), and d) debriefing sheet(s). You can find templates for consenting materials here: EHS REC Forms

Explain how you will obtain voluntary, informed consent for all participant groups. For anonymous questionnaires/surveys, note that implied consent is sufficient, but participants must be presented with the information sheet prior to data collection.

A. In the case of minors (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. Include assenting materials for minors.

B. If your participants cannot read or speak English (or Irish, if your research is aimed at Irish speakers), explain how you will obtain consent.

C. In situations where obtaining free consent may be difficult (e.g., in prisons), explain how you will ensure that free consent is given.

D. When participants are recruited within an organization, include a copy of the letter you will send to the organization's gatekeeper. For example, if you wish to recruit participants from a school setting, include your letter to the principal.

Continue to next page.

Section VI: Care and Protection of Research Participants

A. What is the time commitment for participating in your research? Explain how much time each component will take and the overall average time commitment for each participant. When you have multiple participant groups, explain the time commitment for each group.

Participant Group	Hours	Minutes

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.

B. Identify and explain in detail any potential risks to the participant or researcher from participating in or conducting this study. Note that no study is free of risk, even if none has been previously identified. Identify likely risks relevant to your population, topic, and/or procedures and explain how you will mitigate risk. 'Risk' is defined 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 participants' everyday lives.

D. Identify and explain potential benefits from this study. If predictable risks are identified, please explain how these risks are balanced against anticipated benefits. Explain why these potential benefits of the study justify risks to participants (as outlined above) and participant time commitment (as described in section 6a).

Section VII: Protection of Participants' Confidentiality and Personal Data

A. Who will have access to the data you collect from participants? Please identify who will have access to and control over personal data provided by participants. Include mention of any plans to archive or otherwise share anonymised data with other researchers. Ensure that your information sheet, consent form, Research Privacy Notice and answer to this section are consistent.

B. How will you protect participants' confidentiality? Describe the level of confidentiality you will be able to provide to your participants. Questions to consider: Will their data be anonymous at source (e.g., an anonymous questionnaire)? How will you address issues of confidentiality in situations where participants are known to one another (e.g., focus groups)?

C. How will you protect participants' personal data? What are your plans for data retention, archiving, and destruction? How does your plan align to UL Data Protection Policy? Remember that anonymised data are not personal data after it has been irrevocably anonymised. GDPR applies to personal data up to the point at which it has been anonymised but does not apply once it has been anonymised.

1) How do your data collection, processing, and storage plans adhere to ITD guidance for GDPR compliance? Be aware of differences between personal data, pseudonymised data, and anonymised data. Explain how and whether you will be able to pseudonymize or anonymise participants' personal data partially or completely, and in what time frame. Explain in detail what personal data you will retain for how long and how you will protect it.

2) How long will you store the data and how? Will you archive the data for further analysis by yourself or others (i.e., Open Science)? How will data be destroyed at the end of the storage period? The UL Records Retention Schedule stipulates "Once research project completed, Retain on UL approved repository for the duration specified in the contract with funding provider OR the life of any related patent application, whichever is longer. Otherwise, retain for 7 years. FAIR* research datasets May be retained indefinitely, subject to certain conditions, refer to the Faculty REC and the Research Data Management Unit, Glucksman Library Please be sure you are familiar with the Data Retention Policy and Schedule.

Here is a link to UL policies to consult when designing your procedures to protect participants' personal data.

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Section VIII: Dissemination of Findings to Participants, Stakeholders, and Other Relevant Communities

Explain how you will disseminate your findings both to your wider academic community and to your participants and/or the community or organizations that may have a vested interest in your research. You may, for example, invite participants to request a summary of findings after a certain date or you may offer to make a presentation to a group or organization who might be interested in your findings. Please also indicate if you plan to present your findings at conferences or publish them in academic journals, white papers, or other nonacademic outlets.

Section IX: Indemnity

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.

Where any query arises about whether 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.

Please indicate by way of signature that the research project is covered by UL's insurance policies: PI /

Supervisor Signature: _____

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

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Research Ethics Application Form

Section X: Document Checklist

Use this checklist to indicate the contents of your appendix of study materials:

- ☐ Recruitment materials: All texts Texts and images to be used to reach potential
- ☐ participants Letter to Principal or Gatekeeper
- ☐ Participant information sheet(s) for each group
- ☐ Parent/Guardian information sheet
- ☐ Consent forms for all groups
- ☐ Assent form for participants under age 18
- ☐ Research Privacy Notice
- ☐ Description of any experimental manipulations or other stimulus materials
- ☐ Description of any other participant activities not explained in application Questionnaire/
- ☐ Self-Report Measures
- ☐ Health screening instrument
- ☐ Interview/focus group guide
- ☐ Signed Child Safeguarding Agreement form (all researchers)
- ☐ Outcome of DPIA Screening
- ☐ Other materials not listed here ☐

Section XI: Declarations

The Principal Investigator affirms the following:

The information in this application form is accurate to the best of my knowledge. I undertake to ensure that, if the research proposal is approved by the Ethics Committee, the research team will adhere to the study protocol without unagreed deviation and will comply with any conditions required by the ethics committee.

All named investigators will comply with GDPR and UL/ITD policies regarding handling of all personal data collected from participants. It is the PI's responsibility to ensure compliance regarding data protection.

If relevant, this research has been reviewed by the Health Research Reporting Officer.

The PI will inform the EHS REC of any changes in the protocol via Chair's Decision application.

*Please note that it is the responsibility of the Principal Investigator to ensure that all documentation is complete. This documentation should be submitted by the Principal Investigator. One completed application form and one document containing all collated appendices should be emailed as **two** attachments to EHSResearchethics@ul.ie*

Please affirm:

a.You have included all required documentation, including consent forms, information sheets and research instruments in your appendix of study materials (or where some documentation is not included is there an explanation as to why). ☐ **Yes** ☐ **No**

b. This application form is complete with signatures from the PI, all co-investigators, and your Head of Department/School. ☐ **Yes** ☐ **No**

Please continue next page.

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

The PI must hold a UL employment contract that extends to or beyond the duration of this project.

Does the PI hold a UL employment contract for the duration of this research study? ◯ **Yes** ◯ **No**

Name of Principal Investigator: _____

Signature of Principal Investigator:

Date: _____

Section XII: Additional Submission Guidance

Your completed proposal form must be accompanied by a single appendix of all study materials.

A list of submission dates is available on the EHS REC website. The deadline is usually the first Monday of the month, but this varies due factors such as Bank Holidays. Be sure to consult the schedule of dates and submit your application by midday on the submission date. The deadline is always NOON/MIDDAY. We accept full applications from September through June.

We run a very tight review schedule in which applications are distributed for review as soon after the submission deadline as possible. Late submissions create problems that reverberate through the review process. Please be mindful of this and do not submit late applications. Please do not submit rushed applications that are full of errors in order to make the deadline.

Ensure that all materials relevant to your study are included in your Appendix. See the Checklist in Section X of this form and consult the guidance notes.

Collate all your materials into one document and email as an attachment along with this proposal form. Your application should consist of one completed proposal form and one appendix of study materials (NOT ZIPPED OR LINKED TO YOUR ONEDRIVE).

If you must submit your documents in more than one file, you must explain why in your covering email or your application will be returned.