EHS REC
Application for Expedited Review

TO USE THIS FORM CORRECTLY, DOWNLOAD BY RIGHT CLICKING AND SAVE TO YOUR COMPUTER. THEN OPEN THE DOWNLOADED FILE IN ADOBE ACROBAT. DO NOT COMPLETE IN YOUR BROWSER.

The expedited review pathway is available to researchers whose proposed research poses no more than minimal risk to participants. Conditions:

1. The project involves low risk, non-invasive procedures.
2. All researchers have completed requisite training in the proposed procedures for data collection from human participants.
3. Participants are all adults aged 18 or older.
4. The population(s) to be sampled are not chosen on the basis of any characteristic or circumstance that would put them at greater than minimal risk from participating in your research.
5. The topic you plan to investigate is not sensitive and does not pose any risk to participants that is greater than they would encounter in their everyday lives.
6. Participants will provide informed consent to participate in the study after being fully informed of the research aims, procedures, benefits and risks of participation.

If your project does not meet these criteria for low or minimal risk, then your expedited application will be returned to you, and you will asked to resubmit using the full application form and pathway for ethical review and approval. Please see the EHS REC Guidance Notes for further information about the criteria for expedited review and the review pathways.

The PI must sign below to indicate their agreement with the following statements:

I affirm that the proposed project is a "low risk" project that complies with all of the following conditions:

- The project is **low risk,** as defined above, and does not involve participants, topics or procedures that could potentially put participants at greater than minimal risk.
- All researchers on this project have been trained in the methods used in this study.
- All participants are adults. They will be fully informed about the study aims, procedures, benefits and risks and will provide voluntary, informed consent prior to participation in this study.
- The project is covered by the University of Limerick's indemnity policy.

THE PRINCIPAL INVESTIGATOR IS RESPONSIBLE FOR THIS APPLICATION. IN SIGNING BELOW, YOU CONFIRM THAT YOU HAVE CAREFULLY REVIEWED AND APPROVED ALL INFORMATION PROVIDED WITHIN THIS APPLICATION (AND SUPPORTING APPENDICES) INCLUDING CONTRIBUTIONS TO DOCUMENTATION FROM CO-INVESTIGATORS OTHER THAN YOURSELF.

Principal Investigator

Name _____ Department/School Select One

Signature _____ Date _____

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Project Title:

Start and End Date for Project:

☐ Use Date of Approval or: Start Date:

End Date:

Principal Investigator

Name	
Department/School	Select One
Qualifications	
Phone number for contact	
Email	
Signature	

☐ Please affirm that the PI on this project holds an employment contract with UL for the duration of the project.

Other investigators

Name	Qualification or Role	Department/Affiliation	Signature

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? ◯ **Yes** ◯ **No**

- 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.

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Instructions: 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 more details.

1. Clearly and succinctly, without jargon or technical language, explain the background of your project and your research aims/rationale. Your aims are your intentions and desired outcomes of the project. State your research questions and/or hypotheses.

2. Explain your proposed study design in detail. Identify whether it is experimental, correlational, observational, qualitative or another design. Explain the components of your design: What data will you collect? How will you collect it? From whom will you collect it? Please see the Guidance Document for information about what the committee expects you to include in this section.

3. Describe your sampling and recruitment methods. Explain your inclusion and exclusion criteria. Include information about the organization (e.g., school, NGO) and gatekeepers (e.g. principal, employer) where relevant. Include all recruitment texts and images in your appendix of study materials.

4. Describe your procedures for obtaining and documenting voluntary informed consent. Include all consenting materials in your appendix of study materials.

Continue to next page.

5.Explain the steps you will take to protect participants' confidentiality.

6. Explain your plan for data management: data collection, processing, storage, and analysis. Identify and explain the GDPR-compliance elements of your data storage plan. Identify the individuals who will have access to participants' personal data. Include a Research Privacy Notice (RPN) in the appendix if relevant. Include any plans for data archiving and/or sharing anonymised data for secondary data analysis and make sure this is explained in your information sheet where relevant. Please see the guidance notes and Section VII of the full application form for more details about what to include in this section.

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7. According to the UL Data Retention Policy, "once [a] research project [is] completed, retain [data] 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" (p. 19). Please review this policy and use it to inform your description of where and how long you will retain data collected for your project.

Explain how long you will store the data and for how long. Explain how you will destroy the data at the end of this period. This could include, where relevant, file deletion and document shredding. Documents include the key that links names to codes and signed consent forms.

8. Additional Guidance and Declarations

By submitting this application for expedited review, the PI affirms the following:

- **An appendix of all study materials accompanies this completed application form.**
- **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 all named researchers comply with GDPR legislation.**
- **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.**

Submission instructions:

It is the responsibility of the Principal Investigator to ensure that all documentation is complete.

Expedited reviews are accepted on a rolling basis with no submission deadlines.

The Principal Investigator should submit their application to the EHS REC via email attachment. The application should consist of one completed expedited review application form and one appendix of study materials.

Please type 'new application for expedited review' in your email subject line.

Thank you.

V.18.09.2024.RC