Guidance Notes:

Application to EHS Research Ethics Committee For Ethical Approval

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ETHICS REVIEW PROCESS 3

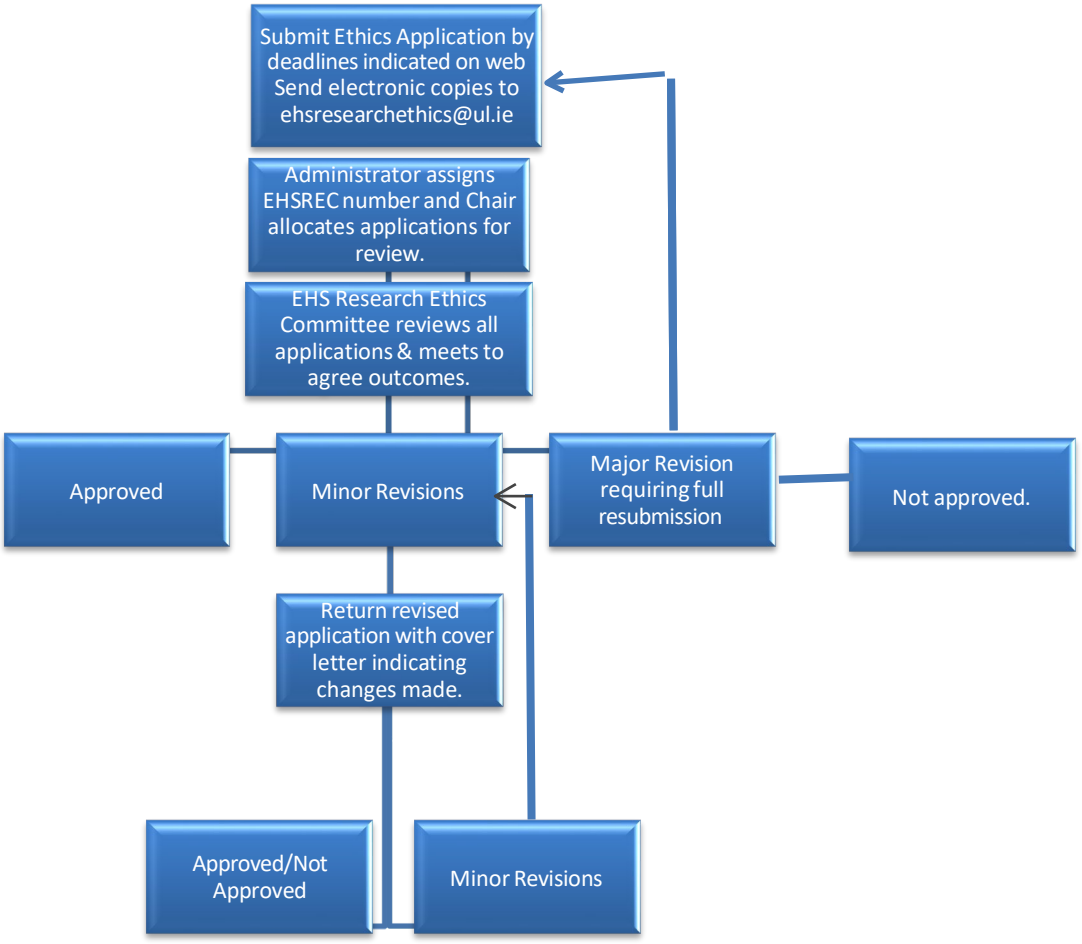
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Submit Ethics Application by deadlines indicated on web Send electronic copies to ehsresearchethics@ul.ie
Administrator assigns EHSREC number and Chair allocates applications for review.
EHS Research Ethics Committee reviews all applications & meets to agree outcomes.
Approved
Minor Revisions
Major Revision requiring full resubmission
Not approved.
Return revised application with cover letter indicating changes made.
Approved/Not Approved
Minor Revisions

INTRODUCTION

All research involving human participants must receive ethical approval. Researchers complete either an application for full review or expedited review to obtain approval to collect data from human participants. Data collection may not commence until approval is granted. Researchers within the faculty of Education and Health Sciences usually apply for ethical approval from the EHS Research Ethics Committee.[1] The PI on the project submits the completed application form and a single appendix of all study materials to the EHS REC via the EHSResearchEthics@ul.ie email address.

The EHS REC does not routinely deem research projects 'exempt' from ethics review. Please contact the EHS Chair if you have questions about whether you should apply for ethical approval for your project. Nevertheless, some research projects do not require ethics approval. For example, secondary analysis of publicly available data sets such as Growing up in Ireland or the National Intellectual Disability Database does not require ethical approval. Systematic reviews do not require ethical approval. Media analyses of publicly available sources (e.g., newspapers, blogs, websites) usually do not require ethical approval. However, analysis of data obtained from social media such as Twitter or Facebook may require ethical approval. The ethics and data protection aspects of research with data obtained from social media sources are still developing, and researchers are encouraged to follow the ethical guidelines of their discipline when they plan to analyse data from these sources. A good beginning point is Social Media Research: A Guide to Ethics.

There are no circumstances in which the EHS REC grants retrospective approval for research after data have been collected. Any data collected from human participants without prior ethics approval may not be used in any reports about the study or its findings including students' final year projects, masters theses, or dissertations, and including any reports compiled for dissemination, written or oral. Data obtained from human participants without ethical approval must be deleted or otherwise destroyed.

For indemnity reasons, the named Principal Investigator (PI) must be an employee of UL with a contract that extends to or beyond the study end-date. Post graduate students may be named at Co-PI on applications. Undergraduate students may not be named as the PI, even on their own project. Students may and should draft their ethics applications, but the researcher identified as the PI on the ethics application form is responsible for the content of the application. The ethics application is a binding document that explains who will carry out what project, how they will administer it, and with whom. Students' learning about research ethics and how to write an ethics proposal should happen independent of the ethics application submission and review process.

Application Components:

1. A completed application form with signatures from each member of the research team. A signature from the Head of Department/School is not required. The PI must sign the document as several places on the form. All signatures should be electronic.
2. An appendix of study materials: a single – NOT ZIPPED – file that contains
    a. All texts images to be used for recruitment (e.g., emails, social media posts), and letters to gatekeepers.
    b. All consenting documents (e.g., information sheet, consent form, assent form for participants under age 18);
    c. Research Privacy Notice for all research except when data obtained from participants are truly anonymous at time of collection. Please use the RPN template provided online and consult the Data Protection Officer at dataprotection@ul.ie if you have any questions about how to edit this document;

[1] When another body has jurisdiction, such as the HSE, TUSLA, or ICGP, the researcher should apply from ethics approval from that organization's REC. When a researcher is part of a multi-site consortium, approval from another institution may be noted by the EHS REC.

d. All data collection tools, stimulus materials, and any other documentation to describe or illustrate what your participants will do and how you will collect what data from them.
e. Approved Procedure/Risk Assessment. Certain procedures for data collection already have EHS REC approval. These procedures are found here. If the researchers plan to use one of these procedures to collect data, they should refer to the procedure by ID number in the application form. In the proposal form the researchers must clearly indicate how the approved procedure applies in the context of the proposed project. For example, if citing the interview/focus group procedure (EHSREC 10_RA01) the PI must provide an interview guide or focus group script that demonstrates the application of this procedure in the appendices of the application. You may wish to apply for a new risk assessment approval. You can find the form here: https://www.ul.ie/ehs/research-ethics/application-guidelines-forms
f. Signed Safeguarding Statement. If your participants will be under age 18, each researcher must sign a safeguarding statement, and these must be included in your appendix of study materials. The Child Protection Guidelines document is here. If you have questions about this you can contact the Safety Officer, Shane McDonnell at ext. 2239 or shane.mcdonnell@ul.ie.
g. Where relevant, a copy of the Data Protection Impact Assessment (DPIA). There is an obligation to complete a DPIA before carrying out certain types of data processing likely to result in a high risk to the rights and freedoms of individuals. There are numerous reasons why you may also need to complete a DPIA, as outlined in the screening form linked above. This extends beyond clinical research and other areas that may traditionally be considered "health research".

Review pathways

There two submission pathways:

1. **Full Review**: This pathway is for all research that involves more than minimal risk related to procedures, topics, or target population. Applications for full review are accepted monthly from September through June. The submission deadline is *usually* noon/midday on first Monday of the month, but this can vary due to bank holidays. Be sure to check our website for the full list of deadlines for the academic year. Applications submitted after 12 noon/midday on the deadline date will not be reviewed until the following month. The EHS REC works on a tight timeline so we can return decisions to PIs as quickly as possible. Therefore, we do not accept late applications.
2. **Expedited review:** This pathway is for all research that involves no more than minimal risk to participants. Applications for expedited review are received on a rolling basis year-round. The expedited application form is streamlined but must be accompanied by a complete appendix of all study materials. If the committee believes the research described in an expedited application may pose greater than minimal risk, the application will be returned and the PI instructed to re-apply via the full review route.

   Application forms for both full and expedited ethics are available here.

Factors to consider when choosing your pathway:

1. **Population: Applications for expedited review may not target any of the following populations for recruitment:**
   - People younger than 18 years old
   - People with significant mental health problems
   - People with a significant learning difficulty
   - People dependent on the protection/under the control/influence of others (e.g. people in care, prisoners, students in supervisory relationships, etc.)
   - Relatives of sick people (e.g. parents of sick children)?
   - People who may have only a basic knowledge of English?
   - Any other population that are potentially vulnerable who may experience greater than minimal risk of harm from participation.

2. **Topic: Applications for expedited review may not investigate topics that could pose more than minimal risk to participants. None of the following topics are eligible for expedited review:**
    - Sensitive personal issues such as suicide, bereavement, gender identity, sexuality, fertility, abortion; criminal or illegal behaviours such as gambling, illicit substance abuse, etc.
    - Actions or behaviours that might diminish self-respect or cause shame, embarrassment or regret.
    - Politically and/or racially/ethically and/or commercially sensitive topics.
    - Topics that may give rise to a risk of loss of employment for the participant.
    - Any other topic that may be considered sensitive?

3. **Procedures: Procedures that pose more than minimal risk are not eligible for expedited review. None of the following procedures are eligible for expedited review:**
    - Use of personal records without consent
    - Deception
    - Placebos
    - Offer of large inducements to participate
    - Audio or video recording without consent
    - Invasive physical interventions or treatments
    - Any other procedure that could put researchers or participants at substantial risk
    - Storage of results or data for less than seven years
    - Any data collection or reporting procedures that are likely to cause pain, discomfort, embarrassment, or changes to lifestyle for participants.
    - Any other procedures that could put participants at greater than minimal risk.

If your project involves any factors listed here, it does not meet the criteria for expedited review, and you must choose the full review pathway. Note that this is not an exhaustive list, and there may be features of projects not listed here that do not meet the criteria for expedited review.

Chair's Decision Application *for Modifications to Previously Approved Studies.* Once an application is approved, the researchers must administer the project as described in the original application. If any changes are made to the list of investigators, research design, recruitment, process of informed consent, data collection or plans for sharing information with relevant communities, these changes should be lodged with the EHS REC via Chair's Decision. Researchers should not implement modifications until the Chair's Decision application has been approved. Note that a project approved via expedited review may be modified via Chair's Decision application IF the proposed modifications would pose no more than minimal risk. If proposed modifications would pose greater than minimal risk, adding minors to a study originally designed only for adult participants, the researchers will have to submit the modification for full review. Consider the long-term development of your project when you decide which route to take for review. If future modifications introduce more than minimal risk, you are advised to take the full review route in the first instance.

It should also be noted that Chair's Decision pertaining to externally approved applications cannot be adjudicated by the EHS REC chair and must be submitted to the original ethical approval body.

GENERAL RECOMMENDATIONS FOR APPLICANTS: FULL REVIEW

The Principal Investigator is responsible for the research project and accountable for the contents of the EHSREC application. Incomplete applications and poorly written applications may be returned for revision without review.

Please note that the guidance included here refers also to the information to be included in the Expedited Ethics Application form.

Your application may not be reviewed by a specialist in your topic area or research methods. Bear this in mind while you put your application together and make sure it is written for the 'intelligent layperson' rather than a subject or methods expert. Explain all technical terms with clear definitions and eliminate jargon.

Review Timeline

- The committee aims to return initial decisions on full applications the week following the monthly committee meeting and aims to return decisions on expedited applications within 10 to 14 working days of receiving the application. The timeline for initial decisions can vary depending on committee workload, annual leave, and the academic calendar.

Possible Outcomes

- There are a range of possible outcomes that may apply to applications as follows:

  a. Approved: In this case, the ethics application is approved and no further amendments are required from the PI.

  b. Minor Amendments. This will apply when there administrative, or minor amendments required. The majority of applications received by the committee historically require minor amendments.

  c. Major Amendments: This will apply in the case of substantive ethical issues, unmitigated risk, or an application of unacceptably low standard. Feedback will be provided by the reviewing team. In this instance the PI **will not be able to resubmit** the application until the next complete cycle. For instance, if an application is returned with a decision of Major Amendments toward the end of March, the PI could not apply again until the May meeting. This approach is to ensure PIs complete ethics applications with due care and attention.

  d. Declined: Where an application presents insurmountable ethical issues, and is unlikely to ever obtain ethical approval even with extensive revision, it will be declined, For instance, where retrospective ethical approval is sought. As with Major Amendments, the PI must wait until the next full cycle of the ethics committee to re-apply.

  e. Withdrawn: In some instances, PIs may choose not to proceed, or it is unnecessary to proceed with the ethical approval process. In this instance, the application is considered to be withdrawn.

  f. Noted – for filing where approval is unnecessary or, for example, approval by a commensurate institution is filed. In this instance, the PI will be furnished with a OA (Other Approval) code, and the project will be noted by EHS REC.

Revisions

The EHS REC will consider a maximum of 2 revisions in addition to the initial application. After this, the application will be rejected. There is some latitude on this, and applications with a small number of minor issues to address may not be penalised. This is at the discretion of the EHS REC members.

Feedback

The feedback you receive will include queries and guidance for revising the document. Please approach this task as you would an editorial decision and reviewer comments: Write a response to the committee keyed to the reviewers' comments. This should be completed on the same sheet as the reviewers provide to you with their comments. Explain the changes that you made, the changes you did not make, and answer any questions posed to you by the committee. **Highlight changes made to documents to make it easy for the reviewers to spot the changes made to your application materials.** Documents with changes that are not highlighted may be returned to PIs.

Noting of Approval from Other Jurisdictions

Researchers whose project involves data collection from human participants (patients or employees) or their records should apply for ethical approval from the corresponding HSE REC. TUSLA and ICGP (Irish College of General Practitioners) also have their own ethical review boards. These bodies have jurisdiction over research projects that include patients, clients, employees, or data from these sites or that are conducted in these premises. Researchers should submit evidence of approval to the EHS REC for noting.

Researchers involved in consortia where a consortium member at another university/ organization applies for and receives ethical approval may submit evidence of this approval to the EHS REC for noting. The researcher is responsible for following the approved protocol.

Noting of approval from another jurisdiction does not constitute approval by the EHS REC. The EHS REC cannot approve modifications to studies approved elsewhere. If you wish to modify your study, the modification must be approved by the institution that granted initial approval.

When you submit evidence of approval from another jurisdiction, make sure that you are named as a co-investigator in the documentation. The documentation should include the title of the project, the research team, and the study ID at minimum. Ideally, you should forward a copy of the approved ethics application along with documentary evidence that it has been approved. Your project will be assigned a unique EHS REC ID number with (OA) (Other Approval) suffix so that the study can be tracked in our records.

Clinical Trials

Competent Authority (CA). In Ireland, this is the Health Product Regulation Authority (HPRA). Research that falls under the category of regulated clinical trials requires HPRA approval and specific insurance to be sought by the University. Please contact the Health Research Reporting Officer Carol O'Sullivan (Carol.Osullivan@ul.ie) with any questions.

TIPS FOR COMPLETING THE EHS REC APPLICATION FORM

COVER PAGE

Title of Project

Ensure that title is clear and concise. The title should be as short a possible but still fully reflect the topic and scope of the project. It should not be a full sentence or overly long. Do not use abbreviated terms or acronyms in the title. Think carefully about whether the title will be readily understood by

potential research participants. You may need to provide an alternative title for participants on consenting materials provided to participants. The alternative title should reflect the meaning of the title on the ethics application form.

Example Title
Novice versus Expert: A Biomechanical Analysis of the Golf Swing

Period for which Approval is Sought

- Select a date from drop down menu when approval is to begin for the project or choose the "date of approval" option.
- Select a date from dropdown menu when approval is to end for the project.
- Indicate what type of project (primarily faculty, undergraduate, postgraduate, shared).
- A minimum of 6 months' approval is recommended to ensure that data collection can be successfully completed within the identified time frame. A maximum of 3 years approval can be requested unless the PI provides a clear rationale for requesting a longer approval period.
- Be advised that EHSREC cannot and will not grant retrospective approval for any research. Any data collected prior to ethical review and approval may not be used any analyses or reports of findings. This includes but is not limited to technical reports, peer reviewed publications, undergraduate or postgraduate theses or dissertations.

Note: for final year project applications, applicants must allow sufficient time to collect data and complete the research.

Principal Investigator
The PI must be an employee of the University of Limerick who has primary responsibility for the design, implementation, completion and management of a research project (i.e., the PI must hold a contract which will not end before the completion date of research study). Details of the PI should be completed in full.

- State the name of the PI.
- Select the name of the Department.
- Indicate the PI's position at the University of Limerick.
- Provide a contact telephone number for the PI.

Other Investigators
Details of Co-PIs (postgraduate students), students (undergraduate or postgraduate), co-investigators (colleagues at other universities or institutions), research assistants, teaching assistants who are research investigators in the project must be listed in 'Other Investigators'. Note the student's programme of study. The researchers listed under 'other investigators' must either provide an electronic signature on the application or provide a handwritten signature on the hard copy of the application before submitting the application to EHSREC. If needed, add a signature page to the appendices to ensure that all members of research team are included in application. If any other investigators are not from UL their organisational affiliation must be indicated clearly in this section (e.g., Prof Mary Smith, Cardiff University, UK)

In the case where an application requires full resubmission all 'other investigators' must sign the resubmitted application.

SECTION 1: ETHICAL ISSUES
This section includes a checklist in which you are asked to identify any aspects of your study design that could cause greater than minimal risk to participants. If you respond 'yes' to any item, you must explain the potential risk and the procedures you have put in place to protect participants.

SECTION 2: APPROVED PROCEDURES, RISK ASSESSMENTS, CHILD PROTECTION & DPIA
This section asks you to confirm if you will use EHSREC or PESSREC Approved Procedures in

your data collection activities, and if so to provide the name and number of the relevant procedure. Please note that it is not required to attach a copy of the procedure in your appendices. This section also asks if you will collect data from any participants who are minors (under 18 years old). If yes, every named researcher must sign a Child Protection Guidance document and include all signed forms in your appendices.

SECTION 3: STUDY DESIGN AND ADMINISTRATION

Section 3a) Study Aims, Research Questions, and Hypotheses

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. There must be a clear relationship of the title to your topic and research question. Include a rationale (justification) for why you designed this study to answer this research question. To receive ethical approval a proposed study must be able to answer the research question and address the stated aims.

Section 3b) Overview of Study

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 the relevant sections from this list to organise the information you include in 3b) to provide a comprehensive summary of your study:

a) *Background and Rationale*: Situate your proposed research in the relevant literature to explain the rationale for your study. Cite relevant academic sources.

b) Study Design. Provide a concise description of the overall design of your project. The design must clearly align with the research question(s). Is your design experimental, correlational, qualitative, or other? If your study is an experiment, describe the experimental and control conditions, independent variables and dependent variables. If your design is quasi-experimental or correlational, identify your predictors, outcomes, mediators, and moderators. If your design is qualitative, explain how you will collect your data. Ensure the questions in your interview guide will elicit information from your participants that is relevant to your research questions. All study materials must be included in your appendices (e.g., stimulus materials, measures, interview or focus group guide).

c) *Procedures/Methods*: Provide a description of the procedures you will use to recruit participants, obtain informed consent, and collect data. Identify key ethical issues and potential risks and explain how you will minimize risk. If your study has multiple stages or strands, use subheadings to organize information about each strand. For multi-stranded project, assign each strand a label (e.g. Strand 1, Strand 2, Strand 3). Explain each strand in terms of participants, data collection and analysis in this section of the application.

1) *Population to be sampled:* Describe the population(s) you plan to sample in terms of your inclusion and exclusion criteria. Identify your proposed sample size(s).
2) *Recruitment:* Explain how you will recruit your participants. How will participants learn about your study? How will you obtain their contact details? How will you distribute your recruitment text to them? Will you work with a gatekeeper? Include all recruitment texts in your appendix of study materials.
3) *Consent:* Explain how you will obtain and document voluntary and informed consent.
4) *Data collection:* Explain who will collect what data from your participants. Explain how and where they will collect the data.
5) Approved Procedures. If you plan to use one of the EHS REC Approved Procedures, name it here with its title and code.

d) *Data Management, Data Protection, and Confidentiality: Recording, Storing, and Processing.* Explain how you will record, process, and store the data in ways that protect participants' confidentiality and comply with data protection laws (GDPR).

1) Explain how you will collect, record, and store your data (e.g., online Qualtrics questionnaire; recorded interviews or focus-groups in person or on Teams; tissue samples, observations).
2) Explain how you will protect participants' privacy and how you will ensure confidentiality of results.
3) Explain steps you will take to pseudonymise and/or anonymise data, and how you will store data.
4) Explain the equipment you will use to record, store and transcribe audio data from interviews and focus groups. Software and platforms must be GDPR/ITD compliant. Researchers should use UL licenced OneDrive for data storage. Use of mobile phones to record interviews is discouraged; if a mobile phone is used, the researcher must follow the ITD Device Management Procedure. Many online transcription programmes are not GDPR-compliant because of the content of the user's agreement. Be sure your recording device and your transcription software are ITD-approved.
5) If you have questions about data protection and/or GDPR, contact the Data Protection Officer, DPO at dataprotection@ul.ie

e) *Plan for Analysis*: Describe your plan for analysis. Your plan must clearly align with your aims, research questions, hypotheses, and the type of data you collect from participants. For quantitative projects, describe anticipated statistical tests. For qualitative projects, describe your analytical approach (e.g., thematic analysis, IPA, grounded theory, discourse analysis) and briefly explain how you code and analyse your data.

- Ensure the content of this section aligns with the subsequent sections of this form and your appendix of study materials.

- Include all study materials related to this section in your appendix of study materials.

Guidelines for research involving children under the age of 18.

- Where relevant, a person in managerial role/responsible adult (e.g., coach, school principal, manager of service organisation) must be informed about your proposed research and grant permission for you to collect data from children under 18 years old. Include the text of the letter/email you will send them in your appendix of study materials.
- You must obtain parent/guardian consent for participation of children under 18 years old. Include an explanation of initial contact between the researcher and the parents. How will they learn about your study? How will they obtain your consenting materials (information sheet, Research Privacy Notice, consent form)? How will they return signed consent forms to you? Note that all information sheets, consent forms and assent forms must be written in plain English. As a starting point, applicants are advised to use short sentences and 1-2 syllable words. Please refer to NALA guidelines for further information.
- Explain how children will be given an opportunity to assent or dissent to participating in the research.
- Explain the steps you will take to ensure sensitive treatment of children from the school/club who do not meet the inclusion criteria or whose opt out of your study. For example, when your research occurs in a school during class time, provide an alternative activity for those students who opt out.
- The UL Child Protection Form must be signed by all members of the research team and included in the appendix of study materials.

Guidelines for questionnaire-based research.

- Explain all variables mentioned in Section 3: what role does each measure serve in your design? Are they predictors, mediators, or outcomes? Make sure every variable mentioned in

Section 3 has a corresponding measure (and citation where relevant) in your appendix of study materials.

- Explain how you will distribute your questionnaire. How will potential participants access your questionnaire? In person or online? How will participants gain access to your online questionnaire?
- Researchers should use Qualtrics to programme questionnaires for online data collection. UL has a licence to this software and it is ITD/GDPR compliant. If you wish to use a different platform for online data collection you should ensure that it is UL/ITD/GDPR compliant and explain this in your application form.
- If paper copies of surveys will be administered in a group setting, then the researcher must explain how participants can opt in or out of the study. For example, if a survey is to be completed by students in a class at UL the researcher might agree with a lecturer to talk to students at the end of a classroom session. The researcher may distribute the surveys to students and leave the room while participants complete (or do not complete) the survey. Students can then place surveys in an envelope or container left in the classroom that the researcher can collect once all students have left the room.

Guidelines for interviews.

- There is an Approved Procedure for semi-structured interviews. Indicate whether you plan to follow this procedure. If you do not, explain your alternative procedures.
- Explain your procedure for meeting with your participant, either online or in-person.
- Explain how you will record the interview and explain how you will protect participants' personal data. Explain how and when data will be pseudonymised and whether it will or can be anonymised.
- If you ask participants to engage in more than one interview, clearly justify the specific purpose and aims of the second interview.
- Explain your timeline for transcription and deletion of recordings.

Guidelines for focus groups.

- There is an Approved Procedure for focus groups. Indicate whether you plan to follow this procedure. If you do not, explain your alternative procedures.
- Focus groups are a valuable research tool; however, it is impossible to guarantee anonymity and confidentiality of participants using this approach. Applicants must identify relevant risks of participating in a focus group discussion on your topics and how you plan to minimize risks associated with potential breaches of confidentiality.
- Explain your procedure for meeting with your participants, either online or in-person.
- Explain how many participants per focus group and how many focus groups you intend to run. Remember the more participants you have, the less each one will have an opportunity to talk. Balance focus group size with the number of focus groups and focus group time commitment to ensure each participant has ample opportunity to make substantive contributions to the discussion.
- Given the structure of a focus group, it is difficult to ensure that a participant can fully withdraw from the study. Any participant could opt not to answer a question or could leave the focus group if they choose. If a participant decides to withdraw from the study after the focus group is over, then their data cannot reasonably be removed without also dropping all other participants in that focus group. In this instance, participants can be assured that none of their statements will be used in any publications or presentations of the work.
- If focus group participants include students in UL, the applicant must clearly identify the relationship between the researcher and participants (e.g., when participants also students in modules that the researcher is involved in). Issues of power arising from dual relationships must be addressed with a clear plan to ensure that students freely choose to participate without feeling obligated to do so.
- If you plan to conduct multiple focus groups with the same participants, explain why more than one is needed to achieve your research aim.

- Include your focus group guide in your appendix of study materials.
- Explain how you will manage recording, processing, and storing of focus group data with procedures, software, and platforms that are UL/ITD/GDPR compliant. Explain your timeline for transcription and deletion of recordings.

Guidelines for research that includes photos or video recordings.
- Explain the purpose of the photographs or video recordings in your study design.
- Specify who will take the photos or record the video (e.g., researcher, participants). Provide contextual details, especially if the photos or videos are of anyone younger than 18 years old.
- If participants take photos or record videos themselves as part of your project (e.g., Photovoice or other participatory projects), provide clear instructions to participants to explain who is and who is not to be photographed. Include your instructions in your appendix of study materials.
- Provide an explanation for how you will analyse the images.
- If any images will be used in knowledge translation or dissemination activities related to the research, include explanation of this in the information sheet and consent form.
- Include explanation in the information sheet about how you will protect confidentiality. Explain how and when images will be deleted/destroyed.

Guidelines for research involving human biological material.
- Always confirm the procedures for dealing with the different categories of waste in your department before you collect any biological material.
- Explain how you will collect, store, and dispose of biological material in your proposal form.
- Biological waste should be disposed of in a biohazard bag. When collecting biowaste such as urine sample, blood samples, contaminated tissues, cotton swabs and gloves, biohazard bags must be used. Biohazard bags must be deposited in a designated biowaste store. Sharp bins must be used for the disposal of needles.

Guidelines for research that involves international partners.
- Provide details about the international partners in an appendix (current post held, university affiliation, summary of CV)
- Provide details about the role of partner(s) including how and when they will contribute to the project.

Guidelines for research that involves an evaluation of an intervention programme.
- The applicant must clearly distinguish between the programme/intervention and the research project in the ethics application.
- The applicant must consider how to provide a choice for people to be involved in the programme while still having the ability to opt out of the research aspect (i.e., evaluation of the programme). Access to the programme cannot be used to inadvertently coerce people into become research participants.
- UL indemnity will only cover the research aspects of the work. It typically does not extend into provision of services (e.g., exercise programme, therapeutic intervention). Professional indemnity or malpractice insurance is usually required for interventions.

Guidelines for research that involves physical activity.
For indemnity purposes, any research involving physical activity must include a health screening tool like the Physical Activity Readiness Questionnaire or another similar questionnaire. Include your screening tool in your appendix of study materials.

Guidelines for projects with multiple research phases or strands.
- When writing up a multi-stranded application, it is advised that each strand/stage be assigned a label (e.g., Strand 1, Strand 2, Strand 3) in this section.
- Each strand then needs to be explained briefly in terms of participants, data collection and analysis in this section of the application.

- Each strand must be discussed in terms of key ethical issues and how the applicant proposes to address these concerns under every section of the EHSREC application. Ensure that the labelling of each strand remains consistent throughout the application.
- If there are several phases or strands in a project, each must be explained clearly with all related appendices noted in this section and labelled for easy access by reviewer. Different phases may require different information sheets and consent forms, depending on the design.

Guidelines for multi-lingual projects.

- Research projects that will involve data collection in languages other than English or Irish must be presented to EHSREC in English or Irish. The data collection tool (e.g., interview guide, survey) must be provided both in the language to be used in the project and in English or Irish.
- The applicant must provide a statement indicating who completed the translation.
- The applicant must provide a statement that the documents written in another language are accurately translated in English or Irish.

Guidelines for research that is reflective or autoethnographic.

- If a proposed project is completely autoethnographic or reflective in design, then it may not always require EHSREC approval. Please contact Chair of EHSREC for advice before submitting this type of application.
- If autoethnography or reflective practice is part of a multi-stranded project, then please refer to above advice about multi-stranded research projects.

SECTION 4: RECRUITMENT OF RESEARCH PARTICIPANTS

Section 4a) Describe your population.

In this section, you are required to 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).:

Clearly explain the methods you will use to recruit participants:

- Describe the population(s) that participants will be recruited from. If you plan to recruit from more than one population (e.g., teachers and students), clearly define each population in this section.
- Clearly explain your inclusion and exclusion criteria. Identify participants' relevant demographic characteristics, including their age.
- Include texts and images of all recruitment materials in your appendix of study materials.
- If you plan to compensate participants for their time and information, explain what the compensation is here. There are disciplinary differences in remuneration for participation, but excessive remuneration is coercive. If your plan for compensation is large, justify it and explain why it is not coercive.
- Explain where and how you will meet with participants and collect data from them. Examples include online via Microsoft Teams, in a UL office or lab, the participants' home, a coffee shop, or a library. Do not recruit participants from a location where alcohol is present.

Guidelines for research involving children in schools.

- Once approval is received from school principal (verbal or written), the researcher can approach parents/guardians and then children with information about the study. The applicant must explain how researchers will recruit children and interact with them. See additional information above for guidance on research with participants younger than 18.

Guidelines for research that involves university students.

- Explicitly tell students that their participation is voluntary and their choice to opt in or out will have no effect on their grades or standing in their course.
- Where possible, the first recruitment contact with students should be a person independent of

the research to address the power aspects of the dual relationship between the student-participant and lecturer-researcher.
- If students are invited to complete a questionnaire, such as to evaluate some aspect of teaching and learning, an independent individual or external person should collect the data and return an anonymised data set to the researcher.
- Remember that students younger than 18 would need parental/guardian permission to participate in research.

Guidelines for managing dual relationships.
- When a dual relationship exists between the lecturer-researcher and student-participants, identify whether power asymmetry could cause potential participants to feel compelled to participate even when the standard practices of informed consent are followed.
- Dual relationships should be acknowledged in the application and the potential impact of the relationship on consent should be explained. Include a protocol for managing or offsetting power dynamics and explain the protocol in the application materials. For example, a gatekeeper independent from the research could recruit participants on the researcher's behalf. Where appropriate and possible, the procedures used to recruit participants via a gatekeeper can be designed to ensure the researcher will not learn who did and who did not volunteer for the study.

Section 4b) Describe your recruitment procedures.

In this section, clearly outline the methods you will use to recruit your participants. This may be purposive, snowball, probability or non-probability sampling for instance. Clearly explain your rationale for method chosen, and outline the procedures you will use. For instance, will you use a social media campaign or a gate-keeper. All texts, images, flyers, posters etc. to be used in all recruitment materials (e.g., emails, social media announcements, letters to gatekeepers, and so forth) should be included in your appendices.

Section 4c) What is your target sample size?

Please advise the maximum number of participants to be included for the study, allowing for attrition, and explain how this number was arrived at.

Section 4d) Participant remuneration

In the case of participant remuneration, please advise how much will be paid and for what purpose. Please contextualise this within disciplinary practice, as this may be normal in some disciplines but not others. Explain and justify any large amounts as this may be perceived as coercive.

Section 4e) Data collection location

In this section, identify where data collection will take place. Please provide details to elaborate on the location(s) and the reason for this choice.

SECTION 5: VOLUNTARY, INFORMED CONSENT

In research involving humans, participants must give voluntary and informed consent. In this section you will describe your consenting procedures. The information sheet, Research Privacy Notice and consent form must be included in your appendix of study materials. For children or any participants who are legally unable to give consent, the applicant must clearly indicate how children will be asked for their assent. Templates for these forms are here.

Informed Participants.

In UL, participants must receive an information sheet that describes the research and what they are asked to do. They must also receive a Research Privacy Notice (RPN), which explains what personal data the researcher will collect and how they will use it. The RPN explains the participants' rights under GDPR. The only time an RPN is not required is under very narrow circumstances when participation is truly anonymous, such as when a questionnaire is distributed online and no participants could not be identified in the resulting data set. When participation is truly anonymous,

GDPR does not apply.

Ensure that all materials are designed for participants' age and reading ability so that they are truly informed. It may be appropriate to use images or photos to help explain aspects of the project to young participants and those who may have limited literacy skills. NALA guidelines should be followed on all recruitment materials including information letters, emails, social media posts, consent forms, flyers, and posters. The NALA guidelines are available here. As a simple rule a reading age of 10 should be aimed for on all recruitment material/questionnaires etc (except when recruiting children less than 10 years of age).

With anonymous surveys, either online or paper-and-pencil, participants must be presented with information about the study. Signed consent is not required. Completing the survey implies consent. For online studies, participants should be asked to click 'yes' to indicate that they read the study information and agree to participate.

If interviews or focus groups are conducted online, the researcher should send the information sheet, consent form, and RPN to the potential participants via email attachment. The researcher should document consent with participants when data are collected remotely. They may download the form, sign it, and return an electronic or paper copy to the research team if they are able to do so. Otherwise, they may simply respond to the researcher by email and affirm that they have read the materials, have no unanswered questions, and agree to participate.

In face-to-face situations, researchers should provide an information sheet, RPN, and consent form to participants. Describe how informed consent will be obtained and by whom (e.g., PI, student researcher, research assistant). Individuals who consent to participate may reply by email and affirm that they read the materials, have no unanswered questions about the study, and agree to participate. The researcher should also affirm at the beginning of the interview or focus group that participants read and understand the study information and that they have no unanswered questions.

In the case that consent is audio or visually recorded in the case of a focus group, interview or other activity (e.g. World Café), transcription of the consent is acceptable once the original activity is deleted.

Risk Appraisal.
Potential participants are typically given time to carefully consider whether they want to get involved in the study. Many projects involve minimal risk to participants, thus decisions about participation can be made relatively quickly by potential participants. Other projects involve substantial risk. The greater the risk the more time required between providing information and participants signing consent. When studies involve a greater time commitment or risk to participants, they may want to discuss the project with others including family, friends, teachers, or a health professional.

If the proposed study involves audio or video recordings, include a separate statement on the consent form for potential participants to opt out of having the interview recorded.

Vulnerable Groups.
For vulnerable groups who may feel unable to decline participation, people with intellectual or learning disabilities, consent should be determined on a case-by-case basis. The Health Services Executive ethics committee advises that a person is unable to give informed consent if they are not able to (1) understand the relevant information; (2) believe the information; (3) remember the information long enough to make a decision; or (4) weigh the pros and cons of participation as part of the decision-making process; (5) express his/her decision verbally, via sign language or an alternative communication approach. In these cases, the PI must clearly explain the procedure to obtain consent and indicate whether any representative or advocate for the participant will be involved in the consent process.

Dual Relationships.
A clear statement of how any relevant dual relationships (e.g., adult/child; lecturer/student, professional/client) will be managed must be included in the information sheet.

Deception.
Some studies involve mild deception. Usually, mild deception takes the omission of information about the hypotheses, study aims, or data collection procedures. In these cases, researchers must give a justification for deception and why the research cannot be done without deception.
Debriefing information, verbal and/or written, should be provided to participants to explain the use of deception.

Right to be Forgotten.
Where possible, participants must be given the option to withdraw from the study with no personal consequences. When participants' data are identifiable to the researcher, the researcher must explain to participants how they may request the withdrawal of their data. This should be mentioned in the information sheet. Be sure that the information in the RPN on withdrawal of data is accurate. If it is not possible to withdraw data (i.e., when data are truly anonymous/have been anonymised, when analysis is complete and reports have been written), this should also be explained in the information sheet. The PI should also consider the ramifications of withdrawal of non-anonymised data once data analysis has commenced and advise the participant accordingly on withdrawal.

SECTION 6: CARE AND PROTECTION OF RESEARCH PARTICIPANTS

6a) Participation time for each participant

- Be realistic in your description of the time commitment you ask of your participants. It is important that the time commitment you describe to your participants matches what you ask them to do. Consider piloting your instrument or protocol to see how long it will take. Remember the time frame includes reading your information sheet and deciding whether to participate.
- For intervention and evaluation studies, the participation time should include only the research activities, not the time when people are attending the programme or intervention.
- Be sure you are consistent across sections in your description of participant demographics, inclusion criteria, sample size, time commitment, and so forth.
- If the research involves different participation groups, describe the total participation time for each of the groups.
- For research that involves evaluation of a programme or intervention, only include the time for research participation,

6b) Multiple testing sessions

- If your participants will be asked to complete several sessions, describe the time commitment for each session and the total time commitment.

6c) Risks

All research involves some level of risk, even if it is minimal or not identified. In this section, identify the relevant risk to participants and explain how you will mitigate these risks. Explain how you have considered the identifiable risks to participants and your plan to manage risk. Provide detailed information on potential risks to participants from procedures or techniques to be employed in the research. For example, all focus groups have the risk of confidentiality breaches.

6d) Potential Benefits of Study

Clearly explain how potential benefits of the study justify the participants' time and information commitments as well as any risks from participation in your research. State how costs and risks are balanced against anticipated benefits.

SECTION 7: PROTECTION OF PARTICIPANTS' CONFIDENTIALITY AND PERSONAL DATA

7a) Access to Data

- See the UL Data Protection Policy for information about how to comply with data protection legislation.
- Identify all the individuals who will have access to participants' data. In the information sheet you may state that the research team will have access to the data so that if researchers join the team, they may access the data.
- Remember that GDPR applies to only to all sets that contain personal data, including pseudonymised data. Pseudonymised data may not contain a person's identity or contact details but may contain information that can trace the data back to their identity. If a key can link participants' responses to their identities, the data are not anonymous. If a participant can be identified in a line of data by their unique set of demographic characteristics, the data are pseudonymous. Keep this in mind when you decide and describe how you will manage your data and protect participants' personal data.
- If you plan to share an anonymised data set with other researchers via Open Science or for your team to conduct additional analyses on the data set, you are obligated to explain this in the information sheet. No existing data can be used outside of the scope or intent of the original project as described to participants, so think about your long-term intentions for the data set and be sure your description of the original intent is broad enough and flexible enough to include data sharing and secondary data analysis if these are possibilities.
- Explain whether participants will have access to their data as part of the research process (e.g., receive a copy of audio or video recording, access to a transcription of interview). Please note that transcripts or recordings of focus groups would typically not be shared given that anonymity and confidentiality would be compromised. An anonymised summary of the focus group discussion could be shared with participants who want to review the key points.
- Refer to the website www.dataprotection.ie if you have any questions or contact the UL Data Protection Officer at dataprotection@ul.ie.

7b Confidentiality

Participants' confidentiality should be maximally protected. Explain how you will protect participants' confidentiality (such as not identifying them in any reports of your findings, by pseudonymising data, by assigning them a unique code number or pseudonym in the data set) and how your data protection procedures will comply with GDPR regulations. To ensure GDPR compliance, use only devices, software, and platforms approved by ITD to record, store, and process data. These include OneDrive for storage, Qualtrics for questionnaire data collection, and Microsoft Teams for online interviews and focus groups. Use of mobile phones to record interviews is discouraged because of risks of data breaches. Commercial transcription software may not be GDPR-compliant, and the user agreement may give the company access to participants' personal data. To protect yourself and your participants, be sure to follow UL/ITD guidelines on what software, platforms, and devices to use. Consult the ITD Device Management Procedure and ITD Data Encryption Procedure.

Store data in your password protected UL-licensed OneDrive account, not a computer hard drive, so that you can share your data with your research team safely and so that your approach to data storage and sharing complies with ITD policies for data protection.

You will likely collect information about participants such as their name, contact details, demographic characteristics, and their responses to your study measures (e.g., questionnaire responses, answers to interview questions, observational data, saliva, and so forth). It is important to remove as much personal data from your data set as possible as soon as possible and completely anonymise the data when possible. The limits to anonymisation must be explained in the RPN.

As long as a participants' identity can be linked back to their responses, your data set is not anonymous. You must explain the steps you will take to protect participants' personal data. Data files should not contain both participants' responses and their identifying information such as their

names or contact details. Always separate these into separate data files. Assign each participant a unique ID number and if necessary, create a separate file to link their unique ID back to their identity. As long as this key exists, the data are not anonymous, they are pseudonymous, and GDPR applies. If your data file contains demographic information about your participants and someone could be identified by their unique combination of characteristics, then the data are pseudonymous, not anonymous, and GDPR still applies. Whether a data set that contains demographic information is pseudonymous rather than anonymous depends, in part, on the population from which the sample was drawn. A participant's data are only truly anonymous when it is impossible for anyone to link their identity to the data they contributed to your research.

Be sure you are up to date with GDPR regulations and UL's policies for GDPR compliance. Make sure you clearly describe how your procedures for protecting participants' personal data are UL/ITD/GDPR compliant. This If you have any questions about this, contact the chair of the EHS REC, the data protection officer, and/or consult ITD policies and procedures.

7c Records Retention

- 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 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.

SECTION 8: FEEDBACK TO PARTICIPANTS AND RELEVANT COMMUNITIES

Explain how you will provide feedback about your study findings to relevant individuals and communities. Describe your plans to share research findings through presentations, publications, theses, dissertations, or other knowledge translation activities).

Explain how aggregate data will be made available to participants. The committee wants to know how you will share your findings with your participants and other individuals in the community, such as parents, the teachers who let you into their classroom, or other stakeholders in the community who have a vested interest in your study. You could, for example, invite participants to contact you after a certain date to obtain a summary of findings, or offer to deliver a presentation on your findings to the teachers and administrators in the school where you collected data.

In some instances, individual results may be provided to participants, for example, personal details about their body composition or sports performance. Given that the PI is responsible for the overall project, any requests for additional information should be directed to the PI rather than to any research student involved in the project. This should be clearly stated in information sheet under the heading, *'What happens at the end of the study?'*

SECTION 9: INDEMNITY

- Indicate either 'YES' or 'NO' as to whether the research project is covered by UL's indemnity policy.
- This section must be electronically signed by the PI.

Indemnity insurance is required for all research conducted by UL employees. Refer to EHSREC website for details regarding UL's insurance policy. If your proposed project is markedly different from projects approved by the EHSREC or if the proposed project involves substantial potential risks to participants, researchers, or the university, then the PI must contact Cliona Donnellan (cliona.donnellan@ul.ie) for confirmation that the project will be insured.

If the proposed research involves invasive procedures, Cliona Donnellan should be contacted and informed. Insurers may need to be consulted, so you should allow several days for a response.

Typically UL indemnity does not extend into provision of services (e.g. exercise programme, therapeutic intervention). Professional indemnity or malpractice insurance is usually required for interventions. Note that UL's current insurance does not cover clinical trials. Seet the clinical trials subsection above and refer to the Health Research Policy.

SECTION 10: DOCUMENT CHECKLIST

Indicate which documents are attached and what documents are not applicable.

Ensure that the application is complete with all required signatures: All members of the research team. The PI's signature is required on the cover page, page 9, and page 10.

SECTION 11: DECLARATION

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

On signing this declaration, the PI is confirming that he/she has checked all documentation and that the application includes all required documentation, including consent forms, information sheets and research instruments etc. (or where some documentation is not Included is there a valid explanation as to why). The PI is also confirming that all required signatures are included.

The PI must sign (electronically or hard copy) to confirm that s/he holds an employment contract at UL that extends beyond the duration of study.

Please note that if the application is incomplete, it will not be reviewed and will be returned to the PI to complete and resubmit.

SECTION 12: APPENDICES

Applicants must create a single electronic appendix of all study materials. All appendices should be referred to in the main application form.

It is strongly recommended that the PI proofread all documents and correct all typos. Check grammar, syntax, and punctuation in all documents, especially those distributed outside UL. We are an institution of higher education and punctuation errors such as missing apostrophes, misplaced apostrophes, misused semi-colons, and misplaced commas cast a negative light on us. Watch out for common spelling mistakes such as 'Principle' Investigator when you mean 'Principal' Investigator, 'effect' when you mean 'affect', and 'it's' 'their's', and 'her's' when you mean 'its', 'theirs' and 'hers'. Semi-colons connect two clauses in a sentence; colons go before lists of things. Things to check when you proofread: spelling, grammar, and punctuation.

Check the readability statistics of your text (In Word, there is a tool under 'spelling and grammar check'). Aim for a Flesch-Kincaid reading level below 8. You can decrease your reading level by writing succinctly and using simpler words.

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

Information Sheets

Information sheet must be included in the appendices. Templates are available the website here. These are ULREG-approved and standardized across the UL RECS. They may be modified, but

your information sheet must include the following information:

- Study title. If the title on the ethics application form is not suitable for the information sheet, a simplified title that links to the meaning of the title on the application form can be used.
- A brief description of what the research is about. The description should explain what a participant will be expected to do.
- The time commitment you ask from your participants.
- Location details. Will data collection occur in a lab on campus, at a place mutually agreed with the participant, or somewhere else?
- Risks and benefits of participating.
- An explanation of how confidentiality will be assured, privacy will be protected, and what the participants' rights are. Do not make promises about anonymity that you cannot keep. Participation in research is not anonymous if the participant is known to the researcher. Reports of findings may be aggregated and anonymised, but data sets are often pseudonymous or otherwise contain some personal data from participants. Explain how you will protect these data and how participants will not be identified in any of your written (published or otherwise) reports.
- If it is possible to withdraw data (e.g., data are not anonymous) from the study explain how to withdraw and the timeframe for withdrawal. This is also explained in the RPN.
- The correct UL Logo must be included on all recruitment information and consent forms. UL brand specifications can be found here.
- Include the contact details (name and UL phone number) of the PI in the information sheet. Do not put personal mobile phone numbers as contact details on flyers, information sheets. Although the main contact is PI, students' names and their UL email addresses may also be provided. Student investigators may provide their personal contact details (e.g. mobile phone number) to participants once they have agreed to participate.
- Include the following EHSREC contact point information on all information leaflets, consent forms, recruitment documents including information letters, emails, social media posts, posters and flyers etc:

  This research study has received Ethics approval from the Education and Health Sciences Research Ethics Committee [insert approval number].

  If you have any concerns about this study and wish to contact someone independent you may contact the Chair, Education and Health Sciences Research Ethics Committee

  EHS Faculty Office, University of Limerick
  Tel (061) 234101
  Email: ehsresearchethics@ul.ie

Informed Consent Form

- Templates for consent forms are found here.
- The consent form must include a title that matches the information sheet.
- Include signature lines for both the participant and the member of the research team who obtains informed consent.
- The consent form must be dated.
- An additional assent form for children under 18 must also be included. For research involving children a participant consent (or assent) form must be provided. Children must be provided with an opportunity to assent or dissent to the research themselves. This form must be written at a reading level to suit age of participants and may need to include images to support comprehension.

When participants include potentially vulnerable adults, signed consent is also needed from a witness whose printed name and signature must be written on the form next to the participant's signature.

Recruitment Texts

Texts of all recruitment materials should be included in the appendix of study materials. Recruitment texts should reference to the fact that the project has been approved by EHSREC and the EHSREC

application number.

Data Collection Tools

- All measures must be included with citations to their sources where available.
- Interview and focus group guides must be included in the appendix of study materials.
- If the research involves physical activity, a participant health screening tool must be included in your protocol and a copy of it must be included in the appendix of study materials.

Common Errors to Avoid

- Insufficient information description of the population to be sampled.
- Incomplete appendix of study materials.
- Insufficient or poorly explained background and rationale for study (Section 3b).
- Incomplete information about some components of multi-component studies. For example, a researcher refers to both questionnaires and interviews in Section 3 but then only describes the questionnaire component of the project in subsequent sections and the appendix only contains the measures and consenting materials for the questionnaire component.
- Inconsistencies across application sections and appendix, for example in descriptions of sample size, time commitment, recruitment procedures, or data collection procedures.
- Leftover text from applications recycled from previous studies.
- Missing contact details, incorrect UL logo.

Applications with appendices in other languages apart from English

For project that include appendices that are translated into other languages apart from English, please attach the translated documents to the application. Also in the ethics application form, you must indicate how the translation is made. It is required that if an IT product such as Google Translate or Chat GPT or similar is used, the translated text must be checked and verified by a native speaker of that language for nuance and accuracy.

Document History:
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