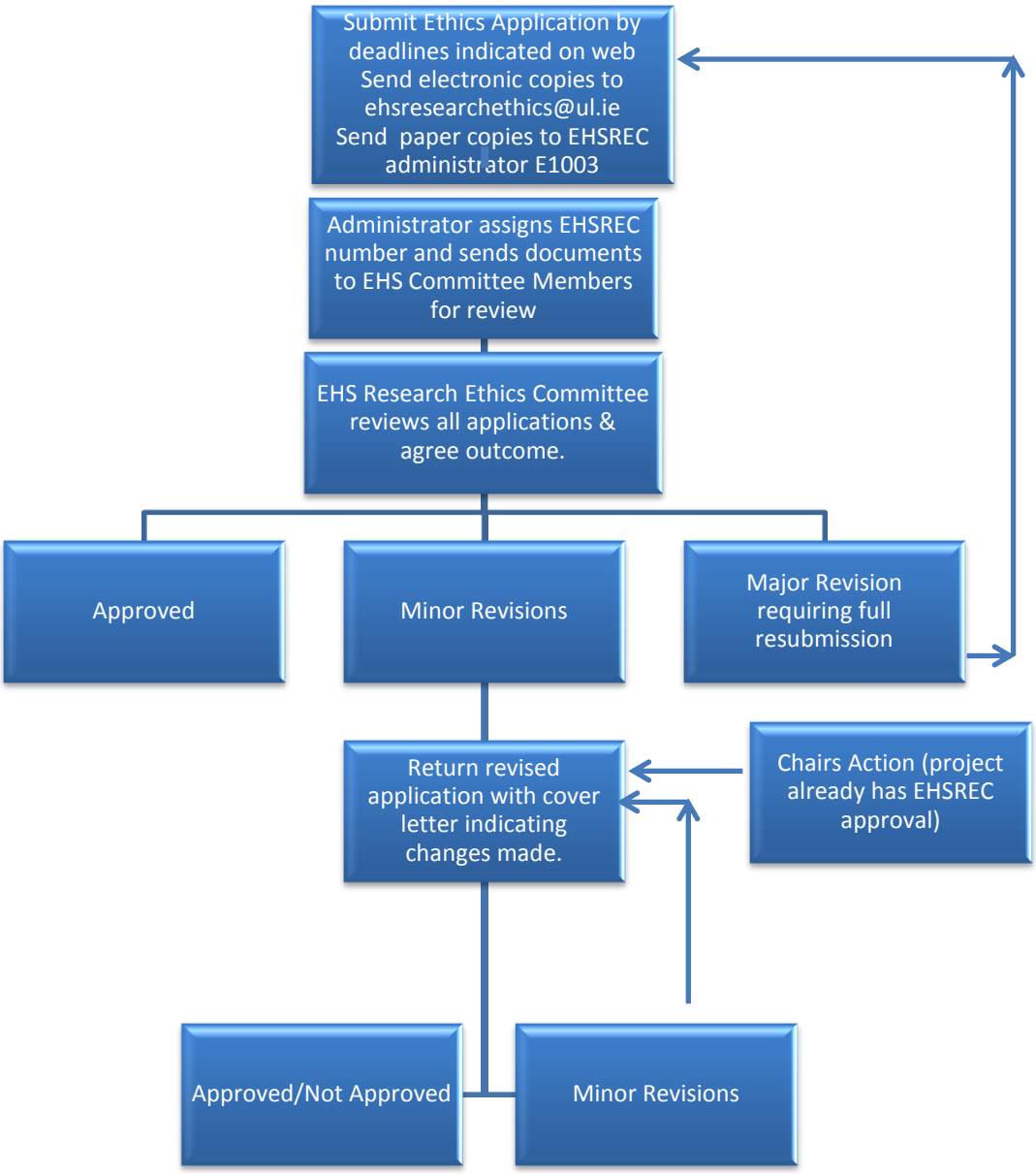
UNIVERSITY of LIMERICK
OLLSCOIL LUIMNIGH

Education
& Health Sciences

Guide for Submitting Application to EHS Research Ethics Committee

Table of Contents

ETHICS REVIEW PROCESS



INTRODUCTION

All research involving human subjects within the Faculty of Education and Health Sciences must be approved by EHSREC. If submitting a proposal for a new project you will need to complete the EHS ethics application form and include any relevant supporting documentation in appendices. The form is compatible with Windows running Adobe Acrobat (includes all UL builds); however, full compatibility with Apple Mac is not guaranteed.

There are some research projects that do not require ethics approval. For example, data mining within existing datasets including Growing up in Ireland, the National Intellectual Disability Database and many others. Engaging in media analysis of publicly available sources (e.g. newspapers, blogsites, websites) does not require ethical approval. Systematic reviews do not require ethical approval and are an excellent mechanism for developing critical appraisal skills and can make a valuable contribution to communities of practice.

Principal investigators are responsible for any ethics application submitted. Although students may draft an application, the final submission must be thoroughly reviewed by the PI. Although contributing to the development of an ethics application provides a valuable learning opportunity for students, it is not the responsibility of EHSREC to provide feedback to students – that is the responsibility of the named PI on any project.

Applications always include items 1-2 below; some may include items 3 or 4

1. Application form with all sections completed.
2. Appendices (e.g. recruitment poster, information letter, consent form, survey, questionnaire, interview guide, focus group script), risk assessment form(s), compiled into a single pdf.
3. Risk assessment form (where appropriate). Citing relevant risk assessment procedures is necessary; however the PI 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.
4. Signed Agreement with UL's Child Protection Policy (where appropriate) by PI and all members of research team if study involved participants under the age of 18. The Child Protection Guidelines document is available on the Human Resources website or at: www.ul.ie/research-ethics If you have a general query related to child protection you can contact Philip Thornton, Safety Office, Human Resources Division at Philip.thornton@ul.ie

Before submitting an ethics application electronically to ehsresearchethics@ul.ie ensure that the full submission is approved by the Principal Investigator and Head of Department. The electronic and hard copy (signed) must contain the same information.

Once approval is received, all research must be carried out as indicated in the original application. If any changes are made to list of investigators, research design, recruitment, process of informed consent, data collection or plans for sharing information with relevant communities a chair's action form must be submitted.

GENERAL RECOMMENDATIONS FOR APPLICANTS

Please consider the following recommendations to promote timely and efficient management of the review of your research ethics application:

- Submit applications at least 2 months before planned start date (refer to website)
- Many applications require minor revisions, thus it is recommended that you build this into your project timeline
- There is typically a 2 week turn-around time for minor amendments
- There is typically a 2 week turn-around time for chair's actions.
- When writing the application, be aware that reviewers may not be specialist experts in the research that you are describing hence avoid use of overly technical language.

When responding to minor revisions the applicant must provide a cover letter outlining where the specific changes were made to the document. Indicate changes in appendices using different font colour or highlighter to alert the reviewer. If a requested amendment is a signature requirement, applicants are required to submit hard and electronic copies, otherwise an electronic version will suffice. A Chair's Action form is not required when completing minor revisions.

In the event that the applicant is asked to consult an approved Risk Assessment Procedure, the applicant can access the procedure from the EHSREC website. When submitting the minor revisions, submit the approved Risk Assessment Procedure. In section B of the application form, state the name and number of the Risk Assessment Procedure you will be using. Please refer to appendices for full list of currently approved Risk Assessment Procedures.

Completion of risk assessment forms for **new procedures** must be submitted to EHSREC. Form available: http://www.ul.ie/ehs/research-ethics

HSE REC Applications
Submission to the HSE Research Ethics Committee is necessary when the research involves patients in hospital (or a GP surgery) or employees of the HSE. Ethical approval should be sought from the HSE REC rather than the University. When the research is approved by the HSE, the PI must copy the approval confirmation from the HSE to EHSREC prior to starting the research.

Clinical Trials
UL is not insured for clinical trials (specific details provided by EU Clinical Trials Directive) involving medication, medical devices, or change to therapeutic practice. UL committees are not authorised to approve such trials in any case, since UL is not an approved clinical trial location.

COMPLETING THE EHSREC APPLICATION FORM

Title Page

APPLICATION TITLE AND PRINCIPAL INVESTIGATOR DETAILS

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. 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 subject information sheets and consent forms. The alternative title should reflect the meaning of the title on the ethics application form.

Example:

Application Title
A Biomechanical Analysis of the differences in the golf swing between novice and expert golfers using qualitative and quantitative methods.

Information Sheet Title
Movement Analysis of the Differences in the Golf Swing Between Novice and Expert Golfers using Video Methods

Period for which Approval is Sought

- Select a date from drop down menu when approval is to begin for the project.
- Select a date from dropdown menu when approval is to end for the project.
- 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 Principal Investigator provides a clear rationale for requesting a longer approval period.
- Be advised that EHSREC cannot approve retrospective research (i.e. research applications where dates for project initiation are before the EHSREC meets to discuss the application)

Note: for final year project applications applicants must allow for sufficient amount of time to gather data and complete the research.

Principal Investigator

The principal investigator is ultimately responsible for the research project. 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 should 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 Principal Investigator (i.e. supervisor of research)

- Select the name of the Department
- Indicate the Principal Investigator's position at the University of Limerick (e.g. Lecturer)
- Provide a contact work telephone number of the Principal Investigator.

Other Investigators

Details of students (undergraduate or postgraduate), research assistants, teaching assistants who are research investigators in the project must be listed in 'Other Investigators'. Programme of study that the student investigator is enrolled in should be stated. The researchers listed under 'other investigators' must sign the hard copy of the application before submitting the application to EHSREC. In larger projects please 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.

Head of Department

State the name of the current Head of Department. Signature also required.

SECTION 1: ELIGIBILITY FOR CHAIR'S ACTION

Has research of a similar nature previously received approval from EHSREC ("Similar" is defined as follows: distinctions only in the researchers involved, differences in the number of subjects involved, extending the original dates of approval, or modifying recruitment strategy small alterations to the procedures being used, and change in the location of the research)? If so you can apply for Chair's Action to your previously approved application. If the application is being submitted for Chair's Action, provide the name and EHSREC number of the previous application. If deemed necessary the Chair may request a full Research Ethics application.

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

SECTION 2: ETHICAL ISSUES

This Section is designed to highlight potential ethical issues that may arise in research involving human subjects. Applicants are expected to carefully consider these ethical issues and prepare a clear rationale for any risks involved in research participation and present a cohesive strategy to safeguard participants. If your research involves participants who are younger than 18 years of age then this must be indicated. **Please see guidelines on the next page.**

SECTION 3: UL/EHSREC APPROVED PROCEDURES

Select the appropriate tick box and provide procedure name and approval number of the UL/EHSREC approved procedure, if applicable. If you are expecting to include participants under the age of 18 then clearly state that you will follow **UL's Child Protection Guidelines** in this section. You must also attach a signed child protection form to your application. This child protection form must be signed by all investigators who will be in contact with the children. Please note that your application must provide clear examples reflecting how you will enact the Child Protections Guidelines in your proposed work.

More details of approved procedures are available on the following websites:
http://www.ul.ie/ehs/ehsrec-approved-procedures

http://www.ul.ie/pess/research-ethics/pess-research-procedures

SECTION 4: STUDY DESIGN AND CONDUCT OF STUDY

Section 4a) Aims of the Research

State main research question and include the aim(s) of the research clearly. The question and aims must relate directly to title of the project. In order to receive ethical approval a proposed study must be able to answer the research question and address the stated aims.

Section 4b) Justification for Choosing this Research Study

Include a short justification for choosing this research study

Section 4c) Description of the Study

In this section use headings to signpost the reader including:

- Brief background of project (1-2 paragraph concise description of rationale and relevance)
- Study Design: provide concise description of overall design of project. The design must clearly align with the research question.
- Participants: provide clear statement about who the participants will be, numbers of participants and if there are different types of participant groups.
- Procedures (methods): describe any procedures in detail including all stages or strands. If study has multiple stages highlight exactly what participants will be doing at each stage and the contact time. Appendices containing information referred to in this section are required (e.g. questionnaire, interview guide, risk assessment procedure, health screen form). Note that all surveys, questionnaires, interview guides and focus group scripts must be in final format. Sample documentation is not acceptable.
- Indicate what type of data will be collected.
- Analytical Approach: Data analysis must clearly align with the research question and aims. For quantitative projects describe anticipated statistical tests. For qualitative projects either describe analytical approach or provide references to support anticipated approach (e.g. grounded theory, phenomenology, discourse analysis)

Guidelines for research involving children under the age of 18

- Indicate when and how children will be given an opportunity to assent or dissent to participating in the research
- The researcher must identify an alternative activity for those not participating or opting out of the study. This would be relevant in research that involves children taking part in research during class time at school. What will the children who opt out of the research do while during this time?
- Parental consent must be obtained for the research.
- An information letter to the person in managerial role/responsible adult (e.g. coach, school principal, manager of service organisation) must be informed of the proposed research. This information letter must be included in the appendices. Indicate how children from the school/club who do not meet the inclusion criteria will be excluded from the research study sensitively.
- The UL Child Protection Guidelines must be reviewed and the UL Child Protection Form must be signed by all research investigators in the study and submitted with the application. Guidelines and Acceptance Form can be accessed on http://www.ul.ie/research-ethics/application-guidelines-forms

Guidelines for research involving a survey or questionnaire

- If a questionnaire/instrument is referred to, clearly state what this instrument will assess. A copy of the instrument must be submitted with the ethics application as an appendix.
- If using online survey tool (e.g. survey monkey) and have requested email address please indicate how you will ensure that this personal information will be removed before the data is stored on research laptops.
- Whenever possible data should be anonymised before it is saved on a computer.

- If hard copies of surveys are to be used in a group setting, then applicant must explain how participants can opt in/out of the study. For example, if a survey is to be completed by students in a class at UL the researcher might make arrangements 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. Researcher collects the completed surveys once all students have left the room.

Guidelines for research involving interviews with participants

- Indicate what the interview procedure involves and provide a fully developed interview guide in the appendices.
- If asking participants to engage in more than one interview, the applicant must clearly justify the specific purpose and aims of the second interview. A fully developed interview guide for the second interview must be provided in the appendices.
- If the interview is to be recorded please detail how that data will be anonymised before storing

Guidelines for research involving human biological material

Always check with the faculty member/technical staff in charge what the procedures are for dealing with the different categories of waste in your department. 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 involving focus groups with participants

- Focus groups are a valuable research tool; however, it is impossible to guarantee anonymity and confidentiality of participants using this approach. Applicants must provide a clear rationale for compromising anonymity/confidentiality of research participants.
- If doing more than one focus group with the same participants explain clearly how the second focus group is unique.
- Fully developed focus group scripts must be provided in the appendices.

Guidelines for research that includes photos or video recordings

- Indicate the purpose of the photographs or video recordings.
- Indicate who in the research is taking the photos or video recordings (e.g. researcher, participants).
- If participants are taking photos or recording video, clear instructions need to be provided for participants regarding when, what, how, and who is to take photographs. This information must be provided in an appendix.
- If images will be analysed, provide details of analytical approach to be used. If any images are to be used in knowledge translation activities related to the research, then applicant must include a specific item on the consent form highlighting this.
- As with all material gathered for research, information must be given to participants on how confidentiality is to be preserved and how/when such material will be destroyed.

Guidelines for research that includes multiple sites

- Some projects are collaborations with other universities or may involve multiple community-based organisations. Such institutions or organisations must be identified in the application.
- There are some reciprocal agreements in place between universities – where an ethics approval from one organisation is accepted by another. Please check with the ethics administrator if your project already has ethics approval from another organisation and include this information in Section 4c of the application form.

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 international partners

- Provide details about the international partners in an appendix (current post held, university partner is affiliated with, brief summary of CV)
- Provide details about the role of partner(s) including how and when they will contribute to the project.
- Clearly describe how data will be shared (this can be addressed in section 8 of the application form).

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 other similar questionnaires.

Guidelines for projects with multiple research phases

If there are a number of phases in a project this must be explained very clearly with all related appendices noted in this section and labelled for easy access by reviewer. Different phases may require different consent forms.

SECTION 5: RECRUITMENT OF RESEARCH PARTICIPANTS

In this section the recruitment method(s) you will use to source participants for the research study should be clearly explained.

- Describe the population that participants will be recruited from.
- Indicate the age/age range of participants.
- If recruiting from more than one group of participants, clearly distinguish between groups in this section.
- State clearly the inclusion/exclusion criteria.
- Ensure that the number of participants stated in 5(c) is consistent with what is referred to in 4(c).
- Indicate where the research will be carried out. If the location of research is a location that will be convenient to the participant, indicate the specific locations, e.g. UL, office, workplace, coffee shop, library). The specific address is not required. Do not recruit participants from a location where alcohol is present.
- If applicable, include the final version of the recruitment email/ poster that will be used to advertise the research in appendices.

Guidelines for research that involves recruiting children from schools

- Once approval is received from principal (verbal or written) the researcher can approach children and parents/guardian with information about the study. The applicant must explain the process of recruitment providing details regarding when and how researcher will engage with potential participants.

Guidelines for research that involves recruiting University Students

- Students should always be made aware that they do not have to participate in the research.

- Students should be reminded that anonymity will be respected.
- Where possible an independent faculty member should be involved in the first contact to recruit students so that a power relationship does not exist.
- Where the research involves the completion of a survey (e.g. evaluating teaching) an independent individual or external person should carry out the research so that only anonymised data is presented to the researcher.
- Consideration needs to be given to the age range of students being recruited. Students <18 will need parental guardian permission as well as their own permission.

Power Relationships

- Investigators should not recruit volunteers if a power relationship exists. Example, students should not recruit students from their own class or teachers in a school should not recruit students they grade.
- Use a 'gatekeeper' (neutral person) who will recruit on your behalf.
- Where appropriate and possible, the gatekeeper should render the data anonymous so you cannot identify who volunteered.

SECTION 6: CONSENT

Informed consent is required for most research. In anonymous or on-line surveys signed consent is not required since completing the survey implies consent of participant. In all other research an information letter and signed consent are required. In this section, describe how informed consent will be obtained and by whom (e.g. PI, student researcher, research assistant). The information sheet and consent form (separate forms) must be included in appendices.

Potential participants are typically given time to carefully consider whether or not they want to get involved in the study. This may involve time for potential participant to discuss the project with others including family, friends, teachers or a health professional. 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.

For children or any participants who may be unable to give consent, the applicant must clearly indicate how the researcher will attend to assent or dissent of participants throughout the project. Information letters and consent forms must be aligned with expected reading levels of participants.

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

If for any reason the PI is not planning to engage in the consent process (e.g. studies involving mild deception of participants) then this must be fully explained. Measures to address the deception must be incorporated as appendices (e.g. written or verbal debrief for participants

after the study). A justification of why 'deception' is required must also be submitted. It should be clear that this research cannot be done any other way.

The option for participants to withdraw from research with no personal consequence is an integral aspect of consent. Indicate how participants can readily withdraw from the study. It is acknowledged that participants completing anonymous questionnaires are unable to withdraw from a study once the form is submitted. If a participant withdraws please describe how any data related to this person will be identified and destroyed. A clear description about how to withdraw from a study must be included in information letter to potential participants.

Ensure that all materials are designed for the age of participants and that reading level is taken into account. It may be appropriate to use images or photos to help explain aspects of the project to younger participants and those who may have limited literacy skills. NALA guidelines should be followed on all recruitment materials including information letters, emails, consent forms and research posters. The NALA guidelines are available on the EHSREC website. 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).

If recruiting students, the applicant must clearly describe how the power relationship (adult/child; lecturer/student, professional/client) will be managed to ensure that potential participants are free to decline involvement or withdraw from a study.

If the proposed study involves audio or video recordings it is recommended that a separate statement is included on the consent form so that people can consent to participate in the study but can opt out of having the interview recorded (e.g. it is not uncommon for teens or people from vulnerable groups to prefer not to be recorded.)

SECTION 7: CARE AND PROTECTION OF RESEARCH PARTICIPANTS

7a Participation time for each participant

- Indicate clearly in hours and minutes the total participation time for each participant (please state a realistic time frame)
- Ensure consistency when indicating participant numbers in Section 4(c), 7(a) and on documentation in the appendices (e.g. information letters).
- If the research involves different participation groups, provide information on 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, not the time when people are attending the programme or intervention.

7(b) Multiple testing sessions

- If there are multiple testing sessions for each participant, provide the breakdown.

7(c) Risks

- All research involves some level of risk – even if it is minimal. The applicant must demonstrate that risks to participants have been carefully considered and that a plan to manage any anticipated risks is in place. Provide detailed information on potential risks to participants from procedures or techniques to be employed in the research. Indicate whether the participants may simultaneously be involved in any other research that PI is aware of. If so, then indicate how PI will ensure that participants are not overburdened.

7(d) Potential Benefits of Study

- In Section 7(c) the risks of the study were described. Clearly explain why the potential benefits of the study justify any risks to participants and the participants' time input. If predictable risks are identified please state how these risks are balanced against anticipated benefits.

SECTION 8: PROTECTION OF PARTICIPANT CONFIDENTIALITY

8a Access to Data

- Provide the names of ALL the individuals who will have access to the data collected from participants.
- If data may be analysed or accessed by other researchers in the future the consent form must indicate this. No existing data should be used outside of the scope or intent of the original project.
- Indicate whether participants will have access to their data as part of the research process (e.g. have 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. Recommend in this instance that an anonymised summary of the focus group be sent out if participants want to review the key points from the discussion.
- It may be useful to refer to the website dataprotection.ie for additional information.
- Note: an external examiner may not have access to the data from a research project. External examiners may only access the research project report, which will include anonymised data.

8b Confidentiality

Data should be anonymised as soon as possible. For example assign each participant a code on data entry sheet. Never store code sheet of names and codes on same laptop as data. Once anonymised, data can be stored on password protected computers. Collected data must be anonymised and stored in a format whereby specific subject information cannot be identified. For example, participant names may be assigned codes and only the data linked to these codes will be stored electronically. Original files should typically be encrypted and stored electronically on principal investigator's password protected laptop computer. Original video recordings should be encrypted and stored on the PI's password protected laptop computer and locked in PIs office when not being used for analysis by the investigators. Statistical data can be encrypted and stored temporarily on a password protected USB key for the duration of the study and on the PI's password protected computer after the study.

- Where applicable a Gatekeeper should be utilised. A Gatekeeper is somebody, outside the research team, who will hold identifying information.
- State on what devices participant data will be stored. Immediately transfer and encrypt audio and video recordings to password protected device then delete original recording from recording device.
- State where recordings or hard copies of participant data will be stored. Typically audio recordings should be deleted immediately after transcription is complete since these cannot be anonymised. If researcher plans to keep the original recordings, then a clear justification must be provided. It is important not to retain personal information for longer than absolutely necessary to meet the aims of the study.

8c Duration of storing data

- UL's standard period of storage for data is 7-10 years after the completion of the research project.
- Indicate how data will be destroyed, e.g. delete file, shred paper records, delete audio files, delete video files. Researchers need to shred identifiable data, e.g. the key linking participant names to codes.

.

SECTION 9: FEEDBACK TO PARTICIPANTS AND RELEVANT COMMUNITIES

This section must be completed by all applicants. Indicate how feedback will be given to participants and to any community group that the research findings would be relevant to. Indicate whether or not individual results will be provided to a participant (if so describe how). Indicate how aggregate data will be made available to participants. Also describe any plans to share research findings more broadly (e.g. through presentations, publications or other knowledge translation activities). Given that the principal investigator 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 letter when describing what happens at the end of the study.

SECTION 10: INDEMNITY

- Indicate either 'YES' or 'NO' as to whether the research project is covered by UL's indemnity policy.

Indemnity insurance is required for all research carried out by UL employees. Please refer to EHSREC website for details regarding UL's insurance policy . In the event that your proposed project is markedly different from projects approved by the EHSREC or if the proposed project involves substantial potential risks to participants or researchers then the Principal Investigator 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. Given that insurers my need to be consulted it is recommended that applicants 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.

SECTION 11: DOCUMENT CHECKLIST

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

Ensure that all appropriate signatures are provided on the application.

SECTION 12: 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 Principal Investigator 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.

Please note that if the application is incomplete it will be returned without consideration by the committee

SECTION 13: APPENDICES

All appendices should be referred to in the main application form. Applicants must create a single electronic document to include all appendices.

It is strongly recommended that applicants check readability statistics of your text (word tool included under 'spelling and grammar check'). Aim for a Flesch-Kincaid reading level below 8. The reading levels can be lowered by using fewer words per sentence and fewer syllables per word.

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. The information sheet must include:

- A title of the study. 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.
- Include a brief description of what the research is about. The description should explain what a participant will be expected to do.
- State the time involved for the participant, where the research will take place, and any risks or benefits to the participant.
- Provide an explanation on the participant's rights to anonymity. If anonymity cannot be guaranteed, then it should not be promised.
- Explain freedom to withdraw from the study at any time.
- Ensure that the language used suits the population you are recruiting from. Avoid technical language and jargon. Use NALA guidelines for improving reading level in all recruitment documents.
- Include the correct UL Logo must be included on all recruitment information and consent forms. UL brand specifications can be found here http://www2.ul.ie/pdf/567279072.pdf.
- Include the contact details (name and UL phone number) of the Principal Investigator must be included on the Information Sheet(s).Do not put personal mobile phone numbers as contact details on flyers, information sheets. Use UL email addresses only. Main contact is principal investigator; students can use their UL email addresses only. Student investigators can only provide their personal contact details (e.g. mobile phone number) to participants once they are recruited onto the study. This is for the protection of personal data of the investigator.
- Include the following EHSREC contact point information on all recruitment documents including information letter and posters.

> This research study has received Ethics approval from the Education and Health Sciences Research Ethics Committee (quote approval number). If you have any concerns about this study and wish to contact someone independent you may contact:
>
> Chairman Education and Health Sciences Research Ethics Committee
> EHS Faculty Office
> University of Limerick
> Tel (061) 234101

Informed Consent Forms

- A participant consent form must be included in the appendices.
- The consent form must include a title of the study. If the title on the ethics application form is not suitable for the consent form, a simplified title that links to the meaning of the title on the application form can be used.
- The consent form must provide a place for both participant and investigator to sign. Also provide space for participant to print name.
- The consent form must be dated.
- 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.
- If research involves children then an information sheet must be provided for the children and for their parents and for principals if research is based in schools.

In the following circumstances a witness signature and printed name are required on consent forms, next to the participant's signature:

- Children
- Potentially vulnerable adults
- Whenever there is a need for a witness, for example, when the freedom to give voluntary consent may be questioned, or a study that includes significant risks.

Recruitment Documents (Email/Poster)

The recruitment email/poster must be included in the appendices. This recruitment document should outline in detail what the project is about, whom to contact for further information, reference to the fact that the project has been approved by EHSREC and the EHSREC application number.

Data Collection Tools

- The questionnaire(s) must be provided in the appendices.
- If planning to engage in qualitative interviews a detailed and complete interview guide must be provided. It is recommended that the applicant pilot the interview guide before submitting the ethics application.
- If planning to engage in focus group research the applicant must provide a detailed list of questions that will be used to guide the discussion. It is recommended that the applicant pilot the focus group script before submitting the ethics application.
- If engaging in research involving physical activity a participant health screen must be provided.
- If the application refers to any approved procedure or to a risk assessment these forms must be included in the appendices.

Common Errors When Submitting

- Insufficient information when describing what the participants will be doing in the study.
- Attachments are referred to but not attached.
- Numbers of participants/time commitment changes throughout the application and on information sheets.
- 'Copy and paste' inclusions from old applications.
- Wrong contact information on information sheet (i.e. chair of old ULREC committee, incorrect phone number of EHSREC contact point.)
- Recruitment documentation does not include PI contact details, EHSREC approval number, incorrect UL logo, student personal phone number or email address.