



## Research Ethics Application Guideline for Undergraduate Students (Version 1, 12 July 2019)

### Basic Requirements

To secure ethical approval, you need to provide:

1. A completed Ethics Application Form for Undergraduate Research Projects that provides a full account of the intended research.
2. All associated documents, including (*if required*) Participant Information Sheet/s, Consent Form/s, Debrief Form/s, task instructions, questionnaires, interview questions, participant recruitment adverts, etc.

### COMPLETING THE ETHICS FORM

It is important that you provide as much detail as possible in completing the Ethics Application Form. The following provides information on each section of the form, and what to include:

#### Part A

#### Boxes A1-A4 are self-explanatory

#### Box A5 Project Summary: What are you intending to do?

In this section, you should be as clear as possible about the rationale behind your proposed study, its aims, the methods to be used, including detail of your intended procedure and tasks, if used your participant sample and recruitment method, and location in which the research will take place. Include information on all of the following:

- Aims of the study
- Brief rationale for the study. What is it based on? Why is it worth doing? Provide evidence from the literature for your rationale.
- The type of methods (e.g. archival research, textual analysis, video recording, lab-based experiment, interview, focus groups, questionnaires, etc.)
- The design of the study. How will the collected data be used? What is being interpreted? What is being measured?
- An explanation of what participants, if you have them, will be asked to do, how long it will take them and what they will experience.
- The participant sample (including online data sources such as social media), if you have them, the size of the sample, the recruitment methods, how do you know that they have consented?

## Part B

### Assessment of Risk

The next section of the form is a series of tick boxes. These identify the most common types of research that raise specific ethical issues. You simply indicate, by ticking a box, whether your proposed research involves any of these participant groups or processes.

**Note that you cannot avoid having to deal with any of these issues simply by ticking 'No'. If you have ticked 'No' and the Ethics Committee considers that you should have ticked 'Yes', then your form will be returned to you to be completed properly.**

Box	Notes
B1. Research involving vulnerable groups (such as children aged 16 years and under; those lacking capacity; or individuals in a dependent or unequal relationship)	This may include children under the age of 16, individuals with known mental health problems or offenders. Please note Disclosure and Barring Service (DBS) will be required to gain data from vulnerable groups. DBS helps prevent unsuitable people from working with vulnerable groups, including children. Discuss with your supervisor
B2. Research involving sensitive topics (such as participants' sexual behaviour; their legal or political behaviour; their experience of violence; their gender or ethnic status, working with deceased estates)	These examples do not represent an exhaustive list, so think carefully about your research and discuss this with your supervisor. Please note that gender or ethnic status are not sensitive per se, sensitivity in relation to areas such as these depends upon the nature of the research.
B3. Research involving a significant element of deception (i.e. beyond the withholding of the research hypotheses where this is necessary for methodological reasons)	Note that even if you are merely withholding the hypothesis and design of an experiment, you must still make sure that you debrief participants properly. This is very unlikely to be approved for NHS related research.
B4. Research involving access to records of personal or confidential information (including genetic or other biological information)	It is unlikely that any student project would involve this. If you do require access to confidential records, this MUST be discussed with your supervisor and you must fully comply with General Data Protection Regulation.
B5. Research involving access to potentially sensitive data through third parties (such as employee data)	This mainly concerns confidentiality and you must fully comply with General Data Protection Regulation.
B6. Research that could induce psychological stress, anxiety or humiliation or cause more than minimal pain (e.g. repetitive or prolonged testing)	In any type of experimental study, participants may find it difficult to perform a task. Think about how participants may feel if they find a task very hard to do (e.g. if they cannot remember much in a memory test). There is no need to be too over-sensitive

	about it, but don't automatically tick 'No' just because you do not intend to inflict pain.
B7. Research that is conducted off campus	Any research that is conducted off campus needs to specify the location and procedures need to be detailed on how the safety of the researcher and the participants will be ensured. This includes travel to archives, filming sites, and off-site photography, visiting Courts of Law etc.
B8. Research involving invasive interventions (such as the administration of drugs or other substances, vigorous physical exercise or techniques such as hypnotherapy, cold water pressor) that would not usually be encountered during everyday life	The examples do not represent an exhaustive list, so think carefully about your research and discuss this with your supervisor.
B9. Research that may have an adverse impact on employment or social standing (e.g. discussion of an employer, discussion of commercially sensitive information)	This applies particularly if you are collecting data from employees. Participants need to be fully informed of the potential implications on their employment status if for example, sensitive data is being collected.
B10. Research that may lead to 'labelling' either by the researcher (e.g. categorisation) or by the participant (e.g. 'I am stupid', 'I am not normal')	This does not just relate to labelling by the researcher. Participants might think themselves stupid or otherwise inadequate if they do not feel that they have done well.
B11. Research that involves the collection of human tissue, blood or other biological samples	Please discuss with your supervisor if this will apply to your project. You will require health and safety training.
B12. Research using procedures that may interact with a pre-existing medical condition in a participant (e.g., a heart disorder in physical exercise studies, allergies in taste studies, epilepsy in computer-based studies).	The examples do not represent an exhaustive list, so think carefully about your research. The most common one here is epilepsy in computer-based studies, so do not overlook this.
B13. Research requiring the use of potentially hazardous equipment or environments.	Please discuss with your supervisor if this will apply to your project. You will require health and safety training.
B14. Research requiring ethical approval from another source (e.g. research in the NHS, prisons, or young offender institutions).	You would be advised to avoid any research setting that would involve ethical approval from another source, as this may prove problematic and time-consuming. Please discuss this with your supervisor.
B15. Research requiring permissions from another source (e.g. schools or businesses/organisations such as archives not in the public domain, copyright permissions to use photographic material).	Permissions to conduct your research from other organisations need to be forwarded to your supervisor AFTER you have secured ethical approval. You cannot begin collecting data until your supervisor has copies of these permissions.

If you have ticked 'Yes' to any of the issues listed above, then you must, in the next section of the form, explain how you will ensure that your study will be conducted ethically. For Psychology students, you should refer to the BPS Code of Ethic for Human Research to ensure that your ethical safeguards are sufficient.

If you are intending to involve any special populations or sensitive issues, you must explain how you have anticipated and planned for any difficulties that may arise, including consideration of any personal risk associated with the research.

The most important aspect of completing this part of the form is that you can show that you have thought things through, that you have appropriate levels of experience and, generally, that you are not being naive about any of the issues that may arise.

For example, if you intend to collect data from children, what experience do you have of working with them? How might children react? What pressures might they feel? How will you be sensitive to, and respond to, these?

If you do not provide sufficient evidence that you are suitably experienced, qualified, or prepared or there are clear risks that you appear to be oblivious to, then your application will be rejected.

## **Part C**

### **Data Management and Storage**

There is the potential for breaches of ethical guidelines at every stage of the research process. The following guidelines should be followed, and discussed with your supervisor, to ensure that your research is being conducted in an ethical manner.

#### **Before data collection**

Ask yourself the following questions about your design, and only proceed if you can answer 'yes':

- *Am I going to be able to make use of the data I am collecting to answer my research questions?* (It is unethical to get people to give their time to generate data that you will not have time to analyse, and it is unethical to get people to give their time to generating data that you will not address your research questions).
- *Do I need to collect new data to answer my research questions?* (It is unethical to use people's time collecting data if information to address your research questions already exists in the public domain).

#### **During data collection**

All paper forms involving personal data (such as consent forms) should immediately be scanned and the electronic files should be stored on your personal OneDrive at Leeds Trinity University. You should not give permission for anyone else to view these files other than your supervisor (who is part of the research team). The paper copies should then be securely destroyed (e.g. using a shredder). Under no circumstances should data be stored on unencrypted USB memory sticks or hard drives. In the event of the hardware failing or theft,

this means that you will lose the data (which means that people have given their time for nothing, which is unethical).

Participants should be allocated a Unique Identifier (ID) code prior to any data collection and only this ID (not personal information such as name, address) should be recorded on any data collection forms (e.g. interviews, questionnaires, computer tasks). If qualitative data such as focus group recordings are going to be transcribed then this should be done as soon as possible, then the original recording deleted and the transcriptions pseudo-anonymised to remove personal identifying information (names). If they are not going to be transcribed then data reduction and analysis should be done as soon as possible, pseudo-anonymised, then the recordings should be destroyed.

### **Data storage and retention**

All digital materials relating to this study, including data, recordings and signed consent forms, will be stored on your OneDrive at Leeds Trinity University for a period of 3 months following your graduation and will then be securely destroyed, in accordance with the [University's Archiving Policy](#).

Copies of some of the reports submitted for the Level 6 research project module are archived with the transcripts or SPSS output tables removed and may be viewed by students at Leeds Trinity University in subsequent years as an exemplar. No report should contain personal or identifiable material.

## **Part D**

### **Ethics Checklist**

The final section of the form comprises a checklist to ensure that you have completed the form properly and that the materials that you will give to participants contain all of the necessary details. The items on the checklist very much reflect the most common mistakes that students make, so treat this checklist with care. The final statement on the form is to be completed by your supervisor, so they will have to confirm that all of the main issues have been addressed.

### **Participant Information Sheet**

The content of the Participant Information Sheet (PIS) should be written in a clear and concise style that is understandable by someone with no prior knowledge of the subject. Avoid using technical terms that people might not understand. The PIS should provide potential participants with the necessary understanding of the purpose, methods, risks and benefits of the research and the planned use of the data to be collected to make an informed decision as to whether to participate in your research project. It will also provide potential participants with details of sources of further information to answer any further questions that they might have. The PIS is likely to be the more detailed of the two documents provided, allowing the Consent Form to be clear, short and concise.

The content and form of each PIS will depend on the nature of, and the level of risk posed by, the specific research project for which they have been designed. In general, however, the

PIS should be a clear document that provides the necessary information while being easily understood by those for whom it has been written (for example it should be age appropriate).

While each PIS is likely to be different, there are some core pieces of information that will normally be included:

- Details of the research project (title, funding source, sponsoring institution, source of ethical review etc.);
- The purpose of the research;
- What participation will involve;
- The benefits and disadvantages/risks of participation;
- A clear statement that participation is entirely voluntary and that participants can withdraw from the project at any time without prejudice, now or in future – including how to withdraw;
- Details of what will happen to the data collected and the results of the research, including:
  - How the data collected will be handled and protected (e.g. confidentiality, anonymisation, data protection);
  - How results will be disseminated;
  - Plans for storage, archiving, sharing and re-use of data (see below for more details).
- Details of who to contact for further information and how to file a complaint.

#### ***The Need for Multiple Versions of the Participant Information Sheet***

You will need separate PIS and Consent/Assent Forms where more than one person must provide consent for a participant (e.g. children or adolescents requiring also parent/ guardian / carer consent). If there are a number of conditions or interventions for the study then all these must be described on the PIS. Where there are different versions of PIS and Consent/Assent Forms there must be adequate version control to ensure that these are paired together.

Please use the following as a template and the subheadings provided.



**Research Ethics Participant Information Sheet Template**  
**(Version 1, 12 July 2019)**

<b>Project Title:</b>
Name of researcher:
School / Institute:
Ethics Approval ID:
Participant Identification Number for this project:
Date:

*(Form to be on headed paper)*

**Participant Information Sheet (Add Version number)** (if you are using multiple Information Sheets indicate whether this is for Child, Parent, Carer or for which condition)

### **1. Invitation and brief summary**

Potential participants should be given very brief information about your study: just enough to decide if they wish to read further. There may be specific issues to address here when you are inviting someone else to give consent on behalf of another, or you are consulting someone to give their opinion on the inclusion of another (e.g. adults not able to consent for themselves).

### **2. What is the purpose of the project?**

What is the nature of what you are proposing? Why are you doing this research? What is already known? How many will be involved in the study? What alternatives are available to potential participants? You should try to keep this brief and avoiding cutting and pasting directly from a protocol; keep your language understandable.

Be careful here not to reveal too much information about the hypothesis or even the independent variables, but remember that for any research within the NHS there is a need for transparency. In this example, the experiment is actually investigating whether people prefer the taste of a drink if it is presented in a branded bottle (e.g. Coca Cola) to when the same drink is presented in an unlabelled container. Clearly, stating this at the outset would be counter-productive so a general summary is provided instead.

### ***Example Opening Sentence***

You are invited to participate in a study of [*provide a brief description of the aims and objectives of the study in lay terms, including what you expect to achieve – see below*]

### ***Example of a Qualitative Study***

You are invited to participate in a study of on-line gaming, investigating the experiences that people have of playing multi-player games on-line. The study aims to provide an understanding of the ways in which people engage with these types of games, the good things and bad things about playing on-line games, and the ways in which game playing has had an impact on your life generally.

### ***Example of an Experimental Study***

You are invited to take part in a study of taste perception. The study explores the ways in which we make judgements about taste and why people may prefer certain drinks to others.

## **3. Who is conducting the study?**

### ***Example for Individual Projects***

This study is being conducted by [*INSERT your name*] as a final-year research project for the degree of [*INSERT degree title*] at Leeds Trinity University, under the supervision of [*INSERT name of supervisor and position*].

### ***Example for Group Projects***

This study is being conducted by a group of undergraduate students as part of a Level [*INSERT level: NB: it may be preferable to specify the year of study rather than the level if the study involves participants who are unfamiliar with what 'Level' means*] module for the degree of [*INSERT degree title*] at Leeds Trinity University under the supervision of [*INSERT name of module tutor and position*]. The student leading this research project is [*INSERT name of a group member to act as point of contact*].

## **4. What does the project involve?**

You should give potential participants an idea of what they should expect if they agree to take part. It is important that you consider their perspective and likely view of any impacts on them, their lives and those close to them. There will be specific issues pertinent to your particular study and the types of participant you intend to recruit which must be considered here (e.g. adults not able to consent for themselves or children / young people).

Explain what the participant will be asked to do and include any other important details that might influence whether or not people want to take part. For example, qualitative studies may involve making an audio or video recording of the session. This needs to be made clear. Give an indication of the amount of time it will take for the participant. If the study involves more than one task, give an estimate for each part. If the study involves more than one session, explain how many sessions there are, how long each one will take, and the timescales involved.

Depending on the nature of the study, this explanation may be more detailed than the brief examples given here. Give an indication of the amount of time it will take for the participant. If the study involves more than one task, give an estimate for each part. Be as accurate as you can and be careful not to under-estimate the time. You should not, for instance, tell participants that something will take five minutes if it really takes an hour.

### ***Example 1***



You will complete a task on a computer that involves making judgements about words that are displayed on the computer screen. You will make responses by pressing keys on the computer keyboard.

### **Example 2**

You will take part in a group discussion with four or five other people about the topic of healthy eating. An audio recording will be made of the discussion.

### **5. Why have I been asked to take part?**

Describe the characteristics needed of participants in order to answer the research question (i.e. why they are suitable) and include details of any incentives/reimbursements.

### **6. Can I withdraw from the project?**

Make it clear that participation is entirely voluntary, so participants can choose not to take part. If they do take part, they can withdraw at any time during the study itself (i.e. literally walk away) without having to give a reason and with no penalty. Indicate whether their data can be withdrawn and up until what time point in the study that data can be withdrawn. In some studies (e.g. online questionnaires), the data of individuals may not be identifiable after collection or once analysis has been started (e.g. focus groups). If this is the case, this needs to be stated in the PIS. It is helpful to divide the information about withdrawing into two parts: (1) withdrawing during the study itself (i.e. stopping participation mid-task and departing) and (2) withdrawal of data after completion of the task. Participants should be given some 'cooling-off' time to reflect on their participation and consider whether they are happy for their data to be used. Specify a set time period and make sure that participants are provided with information about how they can withdraw. The minimum time that should be given for participants to withdraw is one week. For topics that may include more sensitive data, a longer period of reflection will be necessary (a maximum of two weeks). It is relatively unlikely that participants will want to withdraw their data if they have taken part in a simple experimental study that has involved the automatic anonymisation of data, but they should still be offered this opportunity. Do think carefully about whether it will be possible to identify individuals' data at a later date in order to withdraw the data and inform participants accordingly.

### **Example Text for All Types of Study**

Being in this study is completely voluntary - you are not under any obligation to consent and - if you do consent - you can withdraw from participating at any time during your participation and depart without having to give a reason and *[if appropriate]* without it affecting your relationship with *[INSERT Leeds Trinity University, schools or other institutions relating to your research]* in any way. If you wish to withdraw after your participation please email the researcher *[INSERT your email address]*

### **Example Additional Text for Interviews**

You may stop the interview at any time if you do not wish to continue, without having to give a reason. The audio recording *[add video if appropriate]* will be erased and the information provided will not be included in the study. You may also ask for your data to be withdrawn from the study up to *[INSERT number of days or weeks]* after the interview has taken place *[alternatively, specify a date]*, if you decide that you do not wish for your data to be included in the study.

### ***Example Additional Text for Focus Groups***

You are free to leave the focus group at any point and without having to give a reason. Please note, though, that because this is a group discussion it will not be possible to exclude individual data once the session has commenced. This also means that, if you do take part in the whole discussion, it will not be possible for you to change your mind about participation in the study afterwards, as it will not be possible to withdraw your individual data.

### ***Example Additional Text for Questionnaire Studies***

Being in this study is completely voluntary and you are not under any obligation to consent to complete the questionnaire. Submitting a completed questionnaire is an indication of your consent to participate in the study. You can withdraw at any time prior to submitting your completed questionnaire. Once you have submitted your questionnaire anonymously, your responses cannot be withdrawn as it will not be possible to identify which questionnaire is yours.

### ***Example Additional Text for Experiments and Similar Lab-Based Studies***

NB: The word 'experiment' should be replaced with 'study' if not an experiment.

You are free to stop the experiment and leave at any point and without having to give a reason. If you do complete the experiment, you may also request for your data to be withdrawn from the study up to [*INSERT* number of days or weeks] after the date of your participation [*alternatively, specify a date*]. As results will be recorded anonymously, if you wish to withdraw, you will need to provide your participant number. You will be told what this is at the beginning of the experiment. If you do withdraw, either during the experiment or in the period afterwards, all recorded data related to you will be deleted and will not form any part of the study.

## **7. How will the data be dealt with and who will see the results?**

This section covers the related, but distinct, aspects of confidentiality and anonymity. All studies should endeavour to anonymise data as early as possible in the data collection phase, preferably at the start. Provide details of data retention periods for participants (see the **Data storage and retention** section of the relevant application form, but note, these are different for undergraduates and staff or postgraduates).

### ***Example Opening Paragraph***

Your participation in this study is confidential and no information about your participation or individual results will be shared beyond the researcher(s) and supervisor [*or module tutor*].

### ***Example Additional Opening Paragraph for Focus Groups or any other Group Activity***

As you will be participating as part of a group, it cannot be guaranteed that other participants will not reveal details of your participation with others. All participants are asked to respect the privacy of others but please bear in mind that this cannot be guaranteed.

### ***Example Additional Paragraph for Interviews/Focus Groups***

The audio [*or video*] recording of the interview/focus group will only be available to the researcher [*or researchers, if a group project*] and the supervisor]. The recording will be transcribed but your name will not be included and other details that may allow you to be identified will be changed or removed [*NB physical appearance cannot be changed in a video*]. The data will be used for the purposes of this project, and this will form the basis for

a written report. The report will contain the anonymised transcript and this may be viewed by lecturers marking the report, including an external examiner, and will be available to be read by other students in future years\*. In some instances, data may be used by the researcher or the supervisor to form the basis of a publication such as a journal article. There will be nothing in the report or any subsequent publication that will allow any individual participant to be identified.

### ***Example Additional Paragraph for Experiments and Similar Lab-Based Studies***

The data, once collected, will not be identifiable as belonging to any individual participant and will be used only for the purposes of this study. The results will be presented in a summarised form as part of a written report. Only the researcher [*or researchers, if a group project*] and the supervisor will have access to the original data. The report may be read by examiners, including an external examiner and the supervisor and will be available to be read by other students in future years\*. In some instances, anonymised data may be used by the researcher or the supervisor to form the basis of a publication such as a journal article. There will be nothing in the report or any subsequent publication that will allow any individual participant to be identified.

### **7A. Will I be recorded, and how will the recorded media be used? (*if relevant – the production of recorded media*)**

You must ensure that there is a clear understanding of how any recorded media will be used. For instance, if you record a music or theatre performance, you must not publish or broadcast the recording, show it in public, or deposit it in an archive without the performer's consent.

### **7B. Access**

Only the research team will have access to your data and the data will be stored securely.

### ***The following, or similar, paragraph must be included for all final-year projects***

All materials relating to this study, including data, recordings and signed consent forms, will be stored in a secure location at Leeds Trinity University for a period of 3 months following your graduation and will then be securely destroyed in accordance with the [University's Archiving Policy](#).

Copies of some of the reports submitted for the Level 6 research project module are archived with the transcripts or SPSS output tables removed and may be viewed by students at Leeds Trinity University in subsequent years as an exemplar.

### **8. What are the possible benefits of taking part?**

It is likely that you cannot guarantee any specific benefits to the participant, and this should be made clear to potential participants. However, research does deliver wider benefits to society / others with a similar condition and some indirect benefits might be foreseeable for participants themselves.

If you are conducting a quantitative study, make it clear that you will not be providing participants with any 'score' or other feedback on their performance *immediately after completion* (unless, of course, the provision of feedback is an integral part of the study's design, for example to investigate the effects of feedback on further performance).

If you are conducting a qualitative study in which you will be speaking to participants about their experiences, you must make it clear that this is not an opportunity for participants to receive counselling or advice.

### ***Example Text***

There are no anticipated benefits to you of taking part in this study other than any enjoyment you may derive from the study itself or *[if participants include Level 4 students]* the provision of credits towards the research participation requirement for your research methods module.

### ***Example for Task-Based Studies (Including Questionnaires)***

You will not receive feedback on your performance or any kind of score immediately after completing the task. You will not be told how well you performed on the task compared to other people.

### ***Example for Interviews and Discussions***

Please note that although this study is exploring the topic of *[insert topic here]* and you will take part in a one-to-one interview *[or focus group discussion]* this should not be viewed as an opportunity to seek counselling or any other advice from the researcher *[or other participants]*.

## **9. What are the possible risks of taking part?**

You should include details of all significant risks of harm, risks to confidentiality and psychological risk. Try to describe the likelihood of adverse things happening, as well as severity, in a language all potential participants are likely to understand.

### ***Example Text for Computer-Based or Video-Based Studies (not videoing)***

The study involves the use of a computer monitor and the rapid presentation of flashing images. If you have been diagnosed as having epilepsy or any similar medical condition, or if you have ever experienced adverse effects from viewing this type of material *[or performing this type of task]*, then you are advised that you should not participate. If you choose to participate despite this warning, you do so at your own risk.

### ***Allergies***

Allergies: If you are intending to provide participants with food or drink as part of the study, consider the ingredients and provide an appropriate warning. You do not have to list everything, but common allergies and intolerances should be highlighted (e.g. caffeine, nuts, wheat, dairy products). If you are using Biopac, or similar equipment that involves the application of conductive gel, or other substance, to the skin you should warn participants in advance so that those who are aware that they may have an allergic reaction can choose not to participate.

### ***Example Text for Allergies***

The study involves using a conductive gel, which will be applied to your skin. If you are aware of any allergies that you may have to this type of product, or if you have experienced any

adverse reaction in the past to similar products, then you are advised that you should not participate. If you choose to take part, despite this warning, you do so at your own risk.

### **Physiological Risks**

If the study includes prescribed physical activity or supplements that may result in physiological disturbances these should be identified. These disturbances should be accurate highlighting potential discomfort, illness and injury and proportionate (for example the risk and discomfort associate with walking is substantially different to that of sprinting and that of fatiguing exercise). The general principle is that participants should not be surprised by the disturbances of any activities involved in the study.

If the study involves the use of any distressing text or images, you must provide a warning that alerts participants to the nature of the materials that you will be using. This must be proportionate and accurate, so do not say, for example, 'you might find the pictures a bit upsetting' if it is likely that most people would actually find them extremely distressing. If, for example, a video clip features graphic images of bloodshed you must point this out, and not just say that it features 'violence'. The general principle is that participants should not be surprised by the nature of the content of any materials that they encounter during the study, having read the information sheet.

If the study involves discussion of sensitive issues, it is worth pointing out to participants that the nature of the discussion might be distressing.

## **10. What if I require further information about the study or my involvement in it?**

*[insert names, positions and Leeds Trinity University email addresses for student and supervisor].*

### **Example Paragraph**

When you have read this Information Sheet, *[insert name of researcher]* will be happy to discuss it with you further and answer any questions you may have. If you would like to know more at any stage or if, having participated, you wish to withdraw from the study, please contact:

*[insert names, positions and Leeds Trinity University email addresses for student and supervisor].*

## **11. What if I have a complaint or any concerns?**

Any person with concerns or complaints about the conduct of a research study should **contact (Insert name)**, Chair of the (insert School / Institute) Ethics Committee, Leeds Trinity University, Brownberrie Lane, Leeds, LS18 5HD. Email (insert email)

**\*Note:** If your supervisor is (Chair), complaints should be addressed **to (Insert name)**, Vice Chair of the (insert School / Institute) Ethics Committee, Leeds Trinity University, Brownberrie Lane, Leeds, LS18 5HD. Email (Insert email).

Any person with concerns or complaints about data protection relating to a research study should contact the Data Protection Officer, Leeds Trinity University, Brownberrie Lane, Leeds, LS18 5HD. Email: [dataprotection@leedstrinity.ac.uk](mailto:dataprotection@leedstrinity.ac.uk)

In cases where research is being carried out within another organisation (e.g. a School or sport club), there should also be an alternative point of contact within that organisation.

## **Consent Form**

The Consent Form should be separate from the Participant Information Sheet. Each participant should sign an individual Consent Form. In order to maintain confidentiality, no participant should see the name or signature of another participant, so using a signature sheet is not acceptable.

The Consent Form should be a short document that concisely covers the core statements to which the participant is being asked to agree in clear and concise language. The participant should be given the opportunity to agree or disagree with each statement (usually through yes/no tick boxes or signing/initialling each statement) and should be asked to sign, print their name and date the form. Space should also be provided on the Consent Form for the researcher taking the consent to sign, print their name and date the form.

Electronic Consent Forms may be used where appropriate (e.g. online or computer-based studies), but written and signed Consent Forms are preferable for research that poses more than minimal risk to participants. In some types of study, such as those involving the collection of data online, either through an online questionnaire or discussion, it will not be possible to collect signatures. There must, however, be clear evidence that participants have given their consent. For example, an online questionnaire should include a statement at the beginning to the effect that the participant confirms that they have read the Information Sheet and they understand that the completion and submission of the questionnaire constitutes their consent to participate in the study.

While Consent Forms may differ according to the project, they should normally include at least the following or similar statements:

- I have read and understood the Participant Information Sheet;
- I have been given the opportunity to ask questions and have had them answered to my satisfaction;
- I agree to take part in this project;
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason;
- A statement that asks the participant to consent to procedures for handling any personal data collected (e.g. confidentiality, anonymisation, etc.);
- A statement that asks the participant to consent to proposals for data storage, archiving, sharing and re-use for future research;
- (If relevant) A statement that asks the participant to consent to any planned audio or visual recording.

## ***Data sharing and re-use***

It is increasingly a condition of research funding that research data should be shared with other researchers and made open for re-use (within legal and ethical frameworks). The possibility of the re-use of data for research purposes should be considered when preparing a PIS and/or Consent Form. Normally this will take the form of a statement in the Consent Form asking for consent for suitably anonymised research data to be shared for research purposes. Researchers are advised not to unnecessarily restrict the consent requested for

data sharing and data re-use. Unless there is a good reason for placing a restriction on the use of data, Consent Forms should normally clearly request consent for data to be used for research purposes beyond the specific project for which they were collected. Consent Forms should also not unnecessarily restrict consent for use of data to researchers based in LTU, in academia or the UK. Please consult your Supervisor for advice on this.

Please use the following as a template:



**Research Ethics Consent Form Template  
(Version 1, 12 July 2019)**

<b>Project Title:</b>	
Name of researcher:	Ethics Approval ID:
School / Institute:	
Date:	
Participant Identification Number for this project:	

*(Form to be on headed paper)*

**CONSENT FORM (Add version number)** (if you are using multiple Information Sheets indicate whether this is for Child, Parent, Carer or for which condition)

Please initial box

1. I confirm that I have read and understood the Information Sheet for the above study.
  
2. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
  
3. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
  
4. (If appropriate) I understand that the information collected about me will be used to support other research in the future and may be shared anonymously with other researchers.
  
5. (If appropriate) I agree to being contacted for possible participation in future research studies.
  
6. (If appropriate) I understand that the interview / focus group will be audio/video recorded.



7. I agree to take part in the above study. OR I agree to my child taking part in the study.



\_\_\_\_\_  
Name of Participant                      Date                      Signature

\_\_\_\_\_  
Name of Person                      Date                      Signature  
taking consent

If participant is unable to sign, then complete below by person nominated by the participant:

\_\_\_\_\_  
Name of Nominated person                      Date                      Signature

Note: One copy for participant and one for the researcher

## Debrief Form

[*INSERT title of project here*]

There is no template for the debrief as they vary so much, but here is some guidance on why a debrief is important and some of the information you need to include.

### ***Why is the debrief needed?***

Having taken the time and trouble to participate in your study, people are entitled to an explanation of what the study is about, what it was based on, what you are going to do to analyse the data, what you are expecting to find, and what value this might have.

### ***How should the debrief be written?***

In providing information about the study, you should avoid using language that is too technical or jargon-laden. As in the information sheet, you should write in such a way that someone who is not familiar with discipline or subject specific terms could understand. You do not need to provide detailed description of relevant studies but you should provide a brief explanation, in general terms, of what has been found before and how this led to your study.

### ***What information should be included?***

*Hypotheses:* The debrief is an opportunity to explain your study's hypotheses to participants, if it had one. In an experimental study, you should explain what all of the conditions involved so that the participant understands how their participation fits into the experiment as a whole. You should, however, avoid using technical terms such as 'independent variable'.

It is also a good idea to explain why you could not share the full design and the hypotheses with participants prior to their taking part (if applicable). People will, generally, understand why you have had to withhold some information if you take the trouble to explain it to them and make it apparent that you are treating them with the respect that they deserve.

*Aims of study:* If you do not want other participants to know what the study's aims are before they take part, it is a good idea to ask participants not to discuss the study or show the debrief sheet to other people who may yet be asked to participate.

*Reassuring participants:* If the study involved participants performing a particular task, use the debrief to reassure them that the task was one that some, or many, people find difficult. If, for example, you have used a memory task, you could reassure participants that there are many different ways of measuring memory and that this particular task is just one. If they found it difficult, it does not mean that there is anything wrong with their memory, and they shouldn't worry about it.

*Confidentiality:* If the study has involved a focus group, ask participants to respect the privacy of others and not to discuss what was said (or who said what) during the discussion.

*Referral to other agencies:* Depending on the nature of the study, there may be a need to provide referral information should participants have experienced any adverse effects of taking part. For example, a study exploring stress might alert participants to how stressed they actually feel. They might not have thought about it before you interviewed them. You might need to provide contact details for student counselling, the Samaritans, etc.

Most studies will not raise these types of issues, but you do need to use judgement and common sense and be prepared to provide suitable information should it become necessary to do so. There is a balance to be struck here, though. Do not run the risk of producing feelings of anxiety in participants that they might not have experienced had you not suggested it in the debrief!

*Withdrawal:* You should also remind participants of their right to withdraw from the study and of any timescales by which they must withdraw their data should they wish to do so. Information about who to contact to withdraw or ask further questions of should be given again.

*Feedback of results:* Participants should be provided with information on how and when they can receive feedback on the results of the study (noting that this is likely to be group rather than individual results).

*Complaints:* Information about who to contact to make complaints should be provided again, to the Chair of the relevant Ethics Committee for research conduct issues or the Data Protection Officer for data protection issues.

*Complaints:* Information about who to contact to make complaints should be provided again.