# Research Ethics Application Form for Staff and Postgraduate

Completed forms should be submitted to [ethicscommittee@leedstrinity.ac.uk](mailto:ethicscommittee@leedstrinity.ac.uk).

Please direct any queries to [ethicscommittee@leedstrinity.ac.uk](mailto:ethicscommittee@leedstrinity.ac.uk).

To be completed by Principal Investigators, or by postgraduate researchers or taught postgraduate students under the guidance of their Supervisors. The University Research Ethics self-assessment form must be completed first to provide an indication of the need for ethical review and approval prior to commencing the proposed research.

*Office use only:*

Application No: Reviewing REC:

Date Received: Date Approved:

## PART A: Summary

### A1. Title of the research project

Please complete the box below.

### A2: Purpose of the research

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| --- | --- |
| Staff Research Project | Yes / No |
| Postgraduate Research Project | Yes / No |
| Taught Postgraduate student project | Yes / No |
| Other (please specify) |  |

### A3. Contact details: All persons having access to the research data must be named here

#### Principal Investigators, supervisors (PGR projects) or taught Masters supervisor/module lead

|  |  |
| --- | --- |
| Name: (Title/first name/family name) |  |
| Position: |  |
| Faculty/Institute: |  |
| Work Tel No: |  |
| Email address: |  |

|  |  |
| --- | --- |
| Name: (Title/first name/family name) |  |
| Position: |  |
| Faculty/Institute: |  |
| Work Tel No: |  |
| Email address: |  |

#### b. Co-Investigators or co-supervisors contact details:

|  |  |
| --- | --- |
| Name: (Title/first name/family name) |  |
| Position: |  |
| Faculty/Institute: |  |
| Work Tel No: |  |
| Email address: |  |

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| --- | --- |
| Name: (Title/first name/family name) |  |
| Position: |  |
| Faculuty/Institute: |  |
| Work Tel No: |  |
| Email address: |  |

#### c. Postgraduate researcher contact details (PGR projects only):

|  |  |
| --- | --- |
| Name: (Title/first name/family name) |  |
| Student No: |  |
| Programme of study: |  |
| Faculty/Institute: |  |
| Work Tel No: |  |
| Email address: |  |

#### d. Taught postgraduate student contact details (PGT projects only):

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| --- | --- |
| Name: (Title/first name/family name) |  |
| Student No: |  |
| Course of study: |  |
| School/Institute: |  |
| Work Tel No: |  |
| Email address: |  |

### A4. Start and End dates of research

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| --- | --- |
| Estimated Start date of research |  |
| Estimated end date of research |  |

**Note** the research project may not commence until full ethical approval is obtained. The duration of your research project includes the data retention requirements (not just data collection period) – see section D1.

### A5. Funding:

(List funding sources, including internal sources, and status of each)

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| --- | --- |
| Funding body | Approved / Pending / To be submitted |
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### A6. Summary of research

Describe the purpose and background rationale (with evidence from the literature) for the proposed research, as well as the hypotheses/research questions to be examined and the expected outcomes. Do not simply reproduce or refer to the protocol.

This section must be completed in a **language comprehensible to the lay person**. Please explain any technical terms or discipline-specific phrases.

## PART B: The research

### B1. Aims of the research.

Please describe the aims of the research in a language comprehensible to a lay person.

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### B2. Select from the list below to describe your research:

You may select more than one (answer Yes as appropriate)

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| --- | --- |
| Research on or with human participants |  |
| Research working with the data of human participants |  |
| New data collected by qualitative methods |  |
| New data collected by quantitative methods |  |
| New data collected from observing individuals or populations |  |
| Research working with aggregated or population data |  |
| Research using artefacts, sources, texts, published data or data in the public domain |  |
| Research that involves NHS patients, relatives or carers of NHS patients, NHS staff, NHS facilities, or tissue/materials or data from NHS patients. (If your research involves any of these, then an application should be made to the Health Research Authority as NHS ethical approval will be required. There is no need to complete this LTU form) (see <https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/research-ethics-committee-review/applying-research-ethics-committee/> )working with aggregated or population data. |  |
| Research working with human tissue samples (see <https://www.hta.gov.uk/sites/default/files/Code%20E.pdf>  and <https://www.hta.gov.uk/policies/list-materials-considered-be-%E2%80%98relevant-material%E2%80%99-under-human-tissue-act-2004>) |  |
| Research that has a significant environmental impact *(If yes, please give details)* |  |

### B3. Research methodology and design

Please give a full description of the research design and methodology proposed. Qualitative methods and quantitative methods (where used) should be fully described and the choice of method justified. Include what participants will be asked to do (e.g. number of visits, time, interviews etc.) and the duration of time for the participant to complete each stage of involvement. Must be in a language comprehensible to a lay person.

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### B4. Vulnerable participants

Will the participants be from any of the following groups?(Place an X in the final column as appropriate)

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| Children under 16 years of age. Specify age group If working with children under 16. DBS clearance is required. If not yet available, ethical approval may not be granted subject to DBS clearance. |  |
| Adults with learning disabilities |  |
| Adults with other forms of mental incapacity or mental illness |  |
| Adults in emergency situations |  |
| Prisoners or young offenders |  |
| Participants who could be considered to have a particularly dependant relationship with the investigator, eg members of staff, students |  |
| Other vulnerable groups |  |
| No participants from any of the above groups |  |

Please justify the inclusion of the above groups, explaining why the research cannot be conducted with non-vulnerable participants.

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## PART C: Recruitment and consent

### C1. Recruitment

Please state clearly how and by whom the participants will be identified, approached and recruited. Explain each stage of the recruitment process and give details for each sub-group if appropriate. Include any relationship between investigator(s) and participant(s) (e.g. instructor-student).

**Note:** Attach a copy of any poster(s), advertisement(s), email or letter(s) to be used for recruitment.

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### C2. Participants as subjects of the research

Describe the number of participants required to address your research question/s. Provide the rationale for this sample size. If you have a formal power calculation, please replicate it here.

Specify any inclusion or exclusion criteria (e.g. age, gender, location, affiliation, level of fitness etc.) for participants. If you are excluding individuals, then provide a rationale for this.

Describe how you will ensure the recruitment of the targeted sample size.

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### C3. Informed Consent

Please indicate Yes or No to the following question;

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| Will informed consent be obtained from the research participants |  |

If yes, please give details of how informed consent will be obtained. Give details of the steps being taken to provide information about the project to participants and how long participants will be given to consider the information prior to consenting. Attach a copy of the participant Information Sheet/s and any other material used in the consent process, and a copy of the Consent Form/s. If the study requires multiple consent per participant (eg child, parent/guardian/carer) then include the separate Information and Consent Forms for each of these.

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What arrangements will be made for participants who might not adequately understand verbal explanations or written information, or who have special communication needs? How will you ensure children or adolescents fully understand the study and their involvement in it?

How long will participants have to decide whether or not to take part in the research?

If participants are to be recruited from any of the potentially vulnerable groups, **give details of extra steps** taken to assure their protection in providing fully informed consent. Describe any arrangements to be made for obtaining alternative sources of consent (eg parents / guardians / carers). Include any permission / information letter to be provided to the person(s) providing the consent.

For example, describe how informed consent will be obtained from children or adolescents AND their parents/guardians.

**If consent is not going to be obtained from participants, justify why not.**

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### C3. Deception:

Please indicate Yes or No to the following question;

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| Will the research involve any elements of deception? |  |

If yes, please describe the nature and extent of the deception involved. Justify why this it is necessary. Include whether, how and when the deception will be revealed, and who will administer this feedback.   
Deception should be avoided unless the research questions cannot be addressed without it. An appraisal of institutional risk versus reward would need to be conducted.

When deception is deemed indispensable to the methods of a study, the investigators must demonstrate to an ethical review committee that no other research method would suffice; that significant advances could result from the research; and that nothing has been withheld that, if divulged, would cause a reasonable person to refuse to participate. The ethical review committee should determine the consequences for the participant of being deceived, and whether and how deceived participants should be informed of the deception upon completion of the research. (see CIOMS International Ethical Guidelines for Epidemiological Studies 2009 –Commentary on Guideline.)

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### C4. Participant withdrawal:

Describe whether participants will be able to withdraw from the project, and at what stage/s of the project? How will participants be informed of their right to withdraw? How will participants be able to action their withdrawal from the project (eg who will they contact and how)? Is there a time limit for withdrawal? What will be done with the participant’s data if they withdraw? If withdrawal is **not** possible, explain why not.

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### C5. Compensation:

Please indicate Yes or No to the following question;

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| Will individual research participants receive any payment, fees, reimbursements of expenses or any other incentives or benefits to taking part in this research? |  |

If yes, please describe the amount, number and size of incentives and the justification for this. At what stage/s of the study will participants receive the reimbursement? If participants choose to withdraw, how will you deal with this compensation? Please read the Research Ethics: Participant Reimbursement Guidelines

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### C6. Confidentiality:

Please describe the procedures to be used to ensure anonymity of participants and/or confidentiality of data both during the conduct of the research and in the release of its findings.

Describe how and at what stage of the study will the data be de-identified.

If participant anonymity, pseudo-anonymity or confidentiality is not appropriate to this research project, explain why, providing details of how participants will be advised that their data will not be anonymous or confidential.

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### C7. Disclosure:

Please indicate Yes or No to the following question;

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| Will interviews/questionnaires discuss any topics or issues that might be sensitive, embarrassing or upsetting to participants, or is it possible that criminal or other reportable disclosures by the participants could take place during the study? |  |

If yes, please describe how you will deal with these issues

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## PART D: Research Data, Implications and Impact

### D1. Data storage and retention

Please attach a copy of your data management plan (if available) or alternatively provide the following information:

* How will data be accessed
* how will participants’ confidentiality be protected
* who will have control of, and act as the custodian for, the data generated by the project
* is your research externally funded, and if so, has it met the requirements of the funder with regards to data storage and management and any other relevant considerations.
* Information must be provided on the full data lifecycle, from collection to archive.
* **For how long will data be stored?**
* Requirements for the period of data retention are as follows:
* Basic research: 10 years after the completion of the study
* Population health and clinical studies: 20 years after the completion of the study
* Children and adolescent studies: At age 22 years. For children the 3 year statute of limitations does not begin until they reach the age of 18 years and then lasts for up to 4 years.
* Participants who lack capacity for consent: Retain data for 20 years then review whether data needs to be retained.

Describe what research data will be stored, where (e.g. secure server), the measures that will be put in place to ensure security of the data (including if data is to be transferred) and who will have access to it.

Describe whether or how the research data will be shared or disseminated (including by publication).

Describe the method and timing of the disposal of the research data.

Data should only be stored on OneDrive for Business, as part of the official University-managed Office365 subscription. For the process of data collection an encrypted USB drive may be used but the data must then be transferred to OneDrive for storage of the Master Dataset. Data may only be placed on a University-managed laptop if this is synchronised with OneDrive and encrypted on the laptop. The data security status of any software used for data analysis or data collection should be checked with IT services at LTU prior to use.

As soon as the participant consents, the completed Consent Form should be scanned and stored electronically on the LTU server on OneDrive in a separate folder to that of the de-identified raw data. The paper copies of the Consent Forms should then be destroyed using the University’s secure destruction of paper copies process. Any paper copies used for data collection should be scanned and stored on OneDrive with the paper copy then destroyed using the University’s secure destruction of paper copies process.

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### D2. Significance or benefits of the research:

Outline the significance or benefits of the research.

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### D3. Risks of the research:

What health and safety issues (both physical and psychological) may arise from the proposed research for: a) participants; b) researchers; c) other individuals not involved in the research; d) society; e) environment? This should include research that is conducted off campus (e.g. in an archive or library, at a community centre, at a constituency office, during filming, photography, recording or interviewing etc.)? If risks are identified, a risk assessment should be completed identifying the measures that will be taken to **minimise** any risks and the procedures to be adopted in the event of risk occurring.

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### D4. Risk Assessments

Supervisors/PIs must ensure that research activity is conducted in line with Leeds Trinity University’s Health and Safety policy and all risk assessments are completed and signed off as appropriate to the research activity before the work begins.

Please indicate Yes, No or N/A to the following question;

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| --- | --- |
| Have appropriate risk assessment been consulted for this activity? |  |

### D5. Other ethical issues:

Please indicate Yes or No to the following question;

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| --- | --- |
| Are there any other ethical issues raised by the research? |  |

If yes, please specify and describe how these will be addressed.

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## PART E: Declaration: Research Ethics submission checklist

Please complete this check list by answering YES, NO or N/A to each question and submit with your ethics application

|  |  |
| --- | --- |
| All participant recruitment transcripts included (e.g. poster, advert, email,  letter) |  |
| Participant Information Sheet/s included |  |
| Consent Form/s included |  |
| Debrief Form/s included |  |
| Copies of all data collection measures, tests, inventories, questionnaires and interview questions included |  |
| Permissions from other organisations or Research Ethics Committee  Included |  |
| Health and safety has been considered and a risk assessment completed |  |
| Intellectual Property and Copyright issues have been considered  For copyright information, guidance and support see: [https://lib.leedstrinity.ac.uk/iguana/www.main.cls?surl=UsingLibraryCopyright](https://eur02.safelinks.protection.outlook.com/?url=https%3A%2F%2Flib.leedstrinity.ac.uk%2Figuana%2Fwww.main.cls%3Fsurl%3DUsingLibraryCopyright&data=02%7C01%7CJ.Rule%40leedstrinity.ac.uk%7C7bb87ec75e3a451c8c5c08d6ce25764d%7Cdf4c20ba64a84352b3f947881abbc09a%7C0%7C0%7C636923057621843548&sdata=tApKuB7lQrBpi%2FeVNY2LMTMZ1NY7%2BNttdVVAl32Dhus%3D&reserved=0) |  |

## PART E: Declaration:

In completing and submitting this form, I declare that I:

* Have checked the form and the related materials and addressed the ethical issues of the proposed research.
* Have answered all the questions truthfully and to the best of my knowledge and belief, and that I take full responsibility for these responses.
* Have ensured all named researchers have read and confirmed the content of the application
* Undertake to observe ethical principles throughout the programme of research
* Will submit progress reports or participate in audits if required
* Will report any changes affecting the ethical issues, or adverse or unforeseen events arising from the project to my School or Institute Research Ethics Committee.
* Agree to abide by the UK Research Integrity Office’s code of practice for research, the University’s research ethics policy and any other policies, procedures or guidance related to research conduct or integrity issued by Leeds Trinity University.

All named researchers on this form have approved the final version of this submission. As a minimum, the PI/supervisor must provide a signature (below) to verify the above declaration.

PI/Supervisor/signature and date of signing:

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| --- | --- |
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Postgraduate Researcher or PGT student signature and date of signing:

|  |  |
| --- | --- |
|  |  |

Named researcher signature and date of signing:

|  |  |
| --- | --- |
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## PART F: Application submission:

Completed forms should be submitted to [ethicscommittee@leedstrinity.ac.uk](mailto:ethicscommittee@leedstrinity.ac.uk).

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