RKE Ethics and Integrity Application Form

# Basic information

## Project title

Please enter the title of the project, as entered at self-assessment

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## Reference number

Please enter the reference number given to the project when the self-assessment was completed. This is shown in the subject line and at the top of the email with the outcome to the self-assessment.

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# Type of project

**Choose an item.**

## Project Lead

Please enter the name of the ‘Project Lead’ (the person leading the project) at LTU.

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## Other researchers at LTU

Please enter the names of any other researchers (staff or PGR) at LTU who will work on this project. This should include anyone who will have access to research data.

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## External collaborators

Please enter the name of any external collaborators (e.g. outside of LTU) who will work on this project. This should include anyone who will have access to research data (add rows if necessary).

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| --- | --- | --- | --- |
| Name | Institutional Affiliation  | Country in which they are employed | Contact details (email address) |
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# Project details

## Project dates

Estimated start date of research:

**Click or tap to enter a date.**

Estimated end date of research:

**Click or tap to enter a date.**

**Note:** The research project may not commence until full ethical approval is obtained. The duration of your research includes analysis of data, writing up results, and any other related activities, not just the period of data collection.

## Funding

List funding sources (including internal sources):

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| --- | --- | --- | --- |
| Name of funder | URL of funding organisation | Nationality / Country in which funder is based. | Is this funding confirmed (please delete as appropriate) |
|  |  |  | Y/N |
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|  |  |  | Y/N |

## Summary of the research

Describe the purpose and background rationale (with evidence from the literature) for the proposed project, as well as the hypotheses/research questions to be examined and the expected outcomes.

This section must be completed in accessible **language comprehensible to a non-specialist**. Please explain any technical terms or discipline-specific phrases.

Please include in the box a references list including any sources cited in the summary.

Word Limit: 300 words

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## Research design and methods

Please give a full description of the research design and methods proposed. Any methods used should be fully described and the choice of method justified. Include how data will be collected and analysed. Please use accessible language suitable to a non-specialist.

Word Limit: 300 words.

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## Data

Please refer the full [Leeds Trinity University Research Data Management Policy](https://www.leedstrinity.ac.uk/media/site-assets/documents/key-documents/pdfs/research-data-management-policy.pdf) on the requirements for storing and managing research data.

### Personal data

Will your project use or collect personal data this ‘means any information relating to an identified or identifiable natural person (‘data subject’); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person’. See: [What is personal data, ICO.](https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/personal-information-what-is-it/what-is-personal-data/what-is-personal-data/)

**Choose an item.**

### Sensitive data

Will your project use of collect sensitive data sensitive? Sensitive data includes personal data revealing racial or ethnic origin; personal data revealing political opinions, personal data revealing religious or philosophical beliefs, personal data revealing trade union membership, genetic data, biometric data (where used for identification purposes), data concerning health, data concerning a person’s sex life, and data concerning a person’s sexual orientation. See [Special category data | ICO](https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/lawful-basis/a-guide-to-lawful-basis/lawful-basis-for-processing/special-category-data/).

**Choose an item.**

### Data description

What data will you collect or analyse? Please summarise what the data will be. And how you will ensure confidentiality and/or anonymity for personal data. You will have space to set out data management arrangements in Section 1.

Please ensure that you consider the Health and Safety implications of working with data as noted in section 5.

Word limit 150 words.

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## Human participants

### Identification of vulnerable groups

Will your project involve any human participants or their data who might be vulnerable. For an indication of whether participants may be vulnerable, please see the LTU Research and Knowledge Exchange Ethics and Integrity Policy. They might include:

* Children under 16 years of age
* 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 researcher, e.g., members of staff, students
* Other person who may be or become vulnerable in the context of their involvement.

**Choose an item.**

### DBS (Disclosure and Barring Service) Clearance

Will your project require you or others involved in the project to have DBS clearance?
A full explanation of the type of DBS required and how to obtain one can be found [here](https://www.gov.uk/government/collections/dbs-checking-service-guidance--2). It may be required dependent on the location of your project or participant group.

This would normally be required when working with vulnerable adults or children.

 **Choose an item.**

### Summary

If your project includes human participants or their data, please describe who these will be. Give as much detail as possible about their identity and how you will collect data from them, or involve them in the project. Where you answer yes to question [3.6.1](#_Identification_of_vulnerable) or question [3.6.2](#_DBS_(Disclosure_and) you should refer to the specific arrangements related to this.

Word limit: 200 words not including any references.

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### Participant recruitment and incentives/compensation

Please describe how you will recruit participants. This should include selection rationale and processes, how you will identify and reach them and the role of any gatekeepers or intermediaries. Please also describe the use of any incentives or compensation including details of what stage(s) of the study will participants receive the reimbursement at and compensation will be handled if participants choose to withdraw. Please read the [Participant Reimbursement Guidelines](https://www.leedstrinity.ac.uk/media/site-assets/documents/key-documents/pdfs/research-ethics-participant-reimbursement-guidelines.pdf).

Word limit: 150 words.

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### Consent and withdrawal

Please describe arrangements for securing participant consent and withdrawal. Please include as much detail about how and at what point participants will give consent and be able to withdraw, including justifications.

Word limit: 150 words.

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## Sampling information

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 specific individuals, then provide a rationale for this.

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

Word limit: 150 words.

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## Location of the research

Where will the research take place? Please include as much detail as possible about where data collection and analysis will take place, if this is outside of your normal working environment (e.g. LTU campus/working from home) or if it involves human participants (including on campus).

World limit: 100 words.

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## Overseas activity

Describe any activity that will take place outside of the UK, including specifying the location of this activity (names of countries).

Word limit: 100 words.

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## Reporting and dissemination

Describe how you will report and disseminate findings from the project, including details of any publication plans.

Word limit: 100 words.

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## Role of external collaborators

Please describe the role of external collaborators, including detailing what data they will have access to and why their role is necessary in the project.

Word limit: 200 words.

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## Controversial or sensitive topics

Please describe any controversial or sensitive topics involved in the project.

Word limit: 150 words.

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## Military, artificial intelligence, robotics, electrical engineering or computing technology

Please describe any ways that your project might have application in military use or any use of artificial intelligence, robotics, electrical engineering or computing technology. Please ensure that you give detail about the names of technology manufacturers and models where relevant. This does not include standard Microsoft or LTU issued software.

Word Limit 300 words.

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## Environmental factors

Please describe any environmental factors relevant to the project.

Word limit: 200 words.

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## Human Tissues and animals

**Research involving Human Tissue**

Research involving human tissue and materials will be strictly limited. The Human Tissue Act (2004) provides a framework for regulating the collection, storage, and use of human material and tissues and this must be adhered to at all times. Leeds Trinity University does not hold a license for the collection, storage and use of human tissue. However, there are some strictly limited exceptions that permit collection, storage and use of certain limited types of human tissue for research purposes using very specific and limited techniques. Collection, storage and use of these tissues and methods may be possible on a strictly controlled and limited basis on a case-by-case basis. Any work with human tissue should be the subject of a Full Application and detailed documentation and monitoring will be required in any cases that are approved, demonstrating why the RKE activity is permissible without an HTA license being in place.

**Research Involving Animals**

Research involving animals will not be undertaken at LTU. Specifically, no research will be undertaken by LTU staff, approved visiting researchers, PGRs, students or others acting on behalf of the University on LTU premises that requires licensed approval under the Animals in Scientific Procedures Act (1986) and the Amendment Regulations (2012).

In limited cases RKE involving animals may be undertaken in instances where animals are incidental participants in research, where there is no risk of harm to the animal from the RKE, and where the RKE data is collected from human participants interacting with animals (e.g., RKE with police dog handlers or horse-riding communities). In these instances, the RKE should be reviewed in the normal way and all ethical considerations in this document will apply.

Even in these circumstances, research involving animals should consider the following (3Rs):

• Replacement - use of animal cells or if possible non‐animal alternatives.

• Reduction - using fewer animals.

• Refinement - minimise pain and enhance welfare throughout an animal’s life.

For the avoidance of doubt, all LTU staff, approved visiting researchers, PGRs, students or others acting on behalf of the University must be able to opt-out of research involving animals.

If your project involve human tissues or animals, please describe how these will be involved below.

Word limit: 200 words.

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# Ethical considerations and management

## Outline of ethical considerations

What are the main ethical considerations in this project? You should include both the benefits and any risks associated with the research and why they are necessary. You may want to use your answers to the questions above to help in completing this box, for example referring to risks associated with the following (n.b. this list is indicative only and not intended to be comprehensive; you should detail any other ethical considerations relevant to your project):

* the role of human participants and recruitment processes;
* the role and consideration of participants who may be vulnerable;
* personal and sensitive data;
* the location of activity;
* sensitive or controversial topics;
* deception;
* disclosure;
* data gathered via observation or use of social media;
* military involvement or potential for military or oppressive use of research;
* the use of human tissues;
* involvement of animals; and
* any environmental issues.

For an indication of the types of ethical consideration that may be relevant please see the LTU Research and Knowledge Exchange Ethics and Integrity Policy. Please note that the list of ethical considerations here and in the policy are illustrative and are therefore not comprehensive.

Word limit: 500 words.

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## Risk management, controls and mitigations

What risk management, control or mitigation measures will you use in the project to balance benefits with risks and to minimise and manage any risks identified above. Please refer also to any external requirements such as DBS clearance.

Word limit: 500 words.

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## Deception

If deception is involved in your project, please describe the nature of this deception, how this will work and why it is necessary as well as any debriefing associated with deception.

Word limit: 150 words.

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| n/a |

## Disclosure

If it is possible that criminal or other reportable disclosures could take place during the project, please describe what these might be and how you will manage disclosure, including reporting, debriefing and safeguarding measures.

Word limit: 150 words.

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## External approval

Describe any other external approvals required for this project, including as related to overseas activity.

Word limit: 150 words.

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# Health and safety

While staff and PGRs are required to consider possible risks and how to manage them, including those related to health and safety, and include reflection on this in Section 3, they are not expected to include completed and signed risk assessments with their applications. Formal risk assessment must, however, be carried out before any activity takes place. If an application receives approval, it is the responsibility of the project lead to ensure that risk assessment forms are completed for any approved activities and that these are signed by the relevant line manager (in most cases, the Head of School).

Full details of risk assessment procedures, including for work carried out overseas and lone working, and relevant forms are available at the following link: [Risk Assessment Procedures (sharepoint.com)](https://leedstrinity.sharepoint.com/%3Au%3A/r/sites/HealthAndSafety/SitePages/Risk-Assessment.aspx?csf=1&web=1&e=6TbAZX)

More information on health and safety can be found on [the Health and Safety intranet site](https://leedstrinity.sharepoint.com/sites/HealthAndSafety).

For RKE activity that is deemed to be very high risk and that requires approval from the University Research Ethics and Integrity Sub-Committee, completed risk assessment forms will be requested and will be reviewed by a representative of Health and Safety. Applicants will receive communication requesting these forms should the application be referred to the Research Ethics and Integrity Sub-Committee as very high risk.

Please confirm that you have understood that further health and safety risk assessments and approvals may be necessary.

**Choose an item.**

# Data management plan

## Data retention

Check the options in the list below for data storage and retention that apply to your project. You may select more than one.

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| --- | --- |
| Basic research: 10 years after the completion of the study | Y/N |
| Population health and clinical studies: 20 years after the completion of the study | Y/N |
| 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) | Y/N |
| Participants who lack capacity for consent: Retain data for 20 years then review whether data needs to be retained | Y/N |

**Note:** Please be aware that these are requirements and data must be stored for the periods specified below for that type of data.

## Data storage statement

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.

Where consent forms are used, 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.

Please select the option from the drop-down menu to confirm that you have read and understood the above requirements for data storage and retention and will comply with them in your project.

**Choose an item.**

## Data storage arrangements

Describe below what research data will be stored and, if relevant, how it will be shared or disseminated (including by publication). Please comment on any other data storage and retention matters not covered above.

Word limit: 150 words.

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# Standard protocol

This section is only relevant to applications which are to be used as Standard Protocols for multiple staff or student projects.

* A Standard Protocol allows staff to apply for review and approval of projects that may be repeated over time, where they involve substantively similar ethical considerations and risk management.
* Projects to be reviewed/approved under an already approved Standard Protocol will still be subject to self-assessment but the project lead will be able to select a pre-approved Standard Protocol during the self-assessment process.
* A Standard Protocol might apply to multiple staff led projects or level 6 or 7 student projects.
* Standard Protocols will normally only be approved for a time limited period, usually three years.
* The named project lead in this form is responsible for ensuring that any research approved under a Standard Protocol adheres to approved application. This includes the use of materials as set out in the Checklist (section 7.1).

## Summary

Please include details of how the projects undertaken under this Standard Protocol will vary and who will work on them. In particular, please note variations in projects under this Standard Protocol. Please refer to variation in any aspect of content under Section 2 of this form.

Word limit: 300 words.

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## Checklist of Ethical considerations

Will the standard protocol cover research projects that relate to any of the following. This may involve duplication of information given in other parts of the form but is used here to cross reference with new project self-assessments to be undertaken under this Standard Protocol.

|  |  |
| --- | --- |
| human participants | Yes/No |
| collecting or analysing sensitive data | Yes/No |
| personal data not collected by you | Yes/No |
| data about a controversial subject or topic | Yes/No |
| data gathered from social media | Yes/No |
| data that is not already in the public domain | Yes/No |
| environmental risks | Yes/No |
| robotics | Yes/No |
| Artificial Intelligence | Yes/No |
| data on military issues | Yes/No |
| risk of harm to the project team | Yes/No |
| risk of harm to participants | Yes/No |
| risk to the reputation of the University | Yes/No |
| work undertaken with, funded by, and/or sponsored by the Ministry of Defence | Yes/No |
| use of human tissue that **does not** require a license under the Human Tissue Act (2004) | Yes/No |

## Ethical considerations

How might ethical considerations for projects approved under this Standard Protocol vary from the description in Sections 3.

Word limit: 300 words.

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## Risk management, controls and mitigations

How might ethical risk management, controls and mitigations (as described in Section 3) vary for projects approved under this Standard Protocol.

Word limit: 500 words.

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## Data management

Please include details of how the projects undertaken under this Standard Protocol will vary in relation to data management considerations as set out in Section 5.

Word limit: 300 words.

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## Other information

Describe any other considerations relevant to the ethical considerations for projects to be undertaken under this Standard Protocol.

Word limit: 150 words.

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NB projects undertaken within a Standard Protocol may need separate Health and Safety risk assessments and authorisations.

Please confirm that you have understood that further health and safety risk assessments and approvals may be necessary.

**Choose an item.**

# Checklist and declaration

## Checklist

* All participant recruitment transcript(s) (e.g., poster, advert, email, letter, social media post, etc.) **Choose an item.**
* Participant Information Sheet(s) **No**
* Consent Form(s) **Yes**
* Debrief Form(s) **Yes**
* Copies of all data collection measures, tests, inventories, questionnaires, and interview questions **Choose an item.**
* Approvals from other organisations or Research Ethics Committees **Choose an item.**
* Health and safety and risk has been considered (if the application is approved, a formal risk assessment must be completed for all activities, see [)](#_Health_and_safety) **No**
* Intellectual Property and Copyright issues have been considered (for copyright information, guidance and support see [Copyright - Copyright - Leeds Trinity University Library at Leeds Trinity University](https://library.leedstrinity.ac.uk/copyright)) **Choose an item.**

## 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;
* will undertake to observe ethical principles throughout the programme of research;
* will engage with any reporting needs and participate in audits if required;
* will report any changes to the project that have ethical implications not covered by the approved application, or adverse or unforeseen events arising from the project to my Faculty or Institute Research Ethics and Integrity Committee;
* agree to abide by the UK Research Integrity Office’s code of practice for research ([Code of Practice for Research](https://ukrio.org/wp-content/uploads/UKRIO-Code-of-Practice-for-Research.pdf)), the University’s Research and Knowledge Exchange Ethics and Integrity Policy (Research and Knowledge Exchange Ethics & Integrity Policy) and any other policies, procedures or guidance related to research conduct and integrity issued by Leeds Trinity University; and
* have ensured that all named researchers on this form have approved the final version of this submission.

Submit the completed application and any auxiliary documentation via t[he Full Ethics and Integrity Application or Evidence of External Approval form](https://forms.office.com/pages/responsepage.aspx?id=uiBM36hkUkOz-UeIGrvAmlw0_p2n3-RIssCaGuzgbQxUOEM3TkNYVzMwVElUMUlCODlFMkhYUFlJSiQlQCN0PWcu).