Knowledge Exchange (KE) Activity

Application Form for Ethical Review

This form is to be completed by lead applicants who have completed the ‘Knowledge Exchange Self assessment form’ and the form has indicated that full ethical review and approval is required via the KE route prior to commencing the proposed KE activity. Please note that a different form applies if the outcome of your Knowledge Exchange Self assessment form’ was to complete a research ethics application.

Please ensure that the form is completed in full before submission to ethicscommittee@leedstrinity.ac.uk

*Office use only:*

Application No: Reviewing REC:

Date Received: Date Approved:

# PART A: Summary

### A1. Title of activity

Please complete the box below.

### A2: Lead applicant

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| --- | --- |
| Name: (Title/first name/family name) |  |
| Position: |  |
| School/Institute: |  |
| LTU email address |  |

### A3: Other collaborators in the activity (all persons having access to the data must be named here):

|  |  |
| --- | --- |
| Name: (Title/first name/family name) |  |
| Role in the activity: |  |
| Organisation: |  |
| Contact email address: |  |

|  |  |
| --- | --- |
| Name: (Title/first name/family name) |  |
| Role in the activity: |  |
| Organisation: |  |
| Contact email address: |  |

### A4: How long are you requesting approval for?

(maximum 5 years, audit reports may be required in the interim)

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| Duration: | EG: 5 years, one month |
| Commencing from: | Academic year:  |

### A5. Please provide a brief overview, including the aim of the activity and the method of delivery.

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### A6. Please answer Yes or No to all of the following questions

Does the activity…

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| Collect/ contain sensitive data? |  |
| Include a financial incentive to participate? |  |
| Involve your own students, colleagues or employees of the University? |  |
| Take place outside the UK? |  |
| Involve participants who are particularly vulnerable or at risk? |  |
| Involve any participants who are unable to give informed consent? |  |
| Involve data collection taking place BEFORE informed consent is given? |  |
| Involve any deliberate deception or covert data collection? |  |
| Involve a risk to the person(s) carrying out the work or participants beyond that experienced in everyday life? |  |
| Use intrusive or invasive procedures? |  |
| Involve the possibility of incidental findings related to health status? |  |
| Fit into any of the following security-sensitive categories: concerns terrorist or extreme groups; commissioned by the military; commissioned under an EU security call; involves the acquisition of security clearances? |  |

### A7. If you answered yes to any of the questions in A6, please provide more details regarding the specific nature of each response

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### A8. Informed consent

Participants must not be coerced into taking part in KE projects. They should be fully informed as to what their participation involves and, as with a research project, they have the right to decline participation or to withdraw their participation whenever they wish, with no impact on their circumstances as a result of their withdrawal. Informed consent should also include consent for publication of the work (where applicable).

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| --- | --- |
| Will informed consent be obtained from participants of the activity?(insert Yes or No) |  |

If yes, please give details of how it will be done. Give details of any particular steps to provide information. Attach a copy of the Participant Information Sheet and any other material used in the consent and recruitment process, and a copy of the Consent Form. If consent is not going to be obtained, justify why not.

What arrangements will be made for participants who might not adequately understand verbal explanations or written information, or who have special communication needs?

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

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

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### A9. Participant withdrawal

Describe whether participants will be able to withdraw from the activity, and up to what point? How will participants be informed of their right to withdraw? What will be done with the participant’s data if they withdraw? If withdrawal is **not** possible, explain why not.

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### A10. Data storage, access and disposal

**For how long will data be stored? \_\_\_\_ years, \_\_\_\_ months**

Describe what 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), who will have access to it, whether or how it will be shared or disseminated (including by publication) and the method and timing of its disposal.

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 securely. Any paper copies used for data collection should be scanned and stored on OneDrive with the paper copy then destroyed securely.

Requirements for the period of data retention are as follows:

* Basic research: 10 years after the completion of the activity
* 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.

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### A11. Confidentiality and anonymity

Please describe the procedures to be used to ensure anonymity of participants and/or confidentiality of data both during the conduct of the activity and in the release of its findings (where applicable). If participant anonymity or confidentiality is not appropriate to this project, explain why, providing details of how participants will be advised of the fact that data will not be anonymous or confidential.

Data protection: Project leaders must ensure that data is appropriately handled and securely stored in accordance with the Data Protection Act (1998).

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### A12. Health and Safety, Risk Assessments

Project leaders must ensure their KE 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 KE activity before the work begins.

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| Have appropriate risk assessments been consulted for this activity?(insert Yes or No) |  |

Outline the potential risks to: a) participants; b) project leaders; c) other individuals not involved in the activity; d) society; e) environment and the measures that will be taken to minimise any risks and the procedures to be adopted in the event of mishap.

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# PART B: Submission and Declaration

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

* 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 applicants have read and confirmed the content of the application
* Undertake to observe ethical principles throughout the activity proposed
* 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 Faculty or Institute Research Ethics and Integrity Committee.
* Agree to abide by , the University’s research and knowledge exchange ethics and integrity policy and any other policies, procedures or guidance related to research and knowledge exchange conduct or integrity issued by the University.

# B1: Knowledge Exchange 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 exists for the proposed activity |  |
| Intellectual Property and Copyright issues have been consideredFor 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) |  |

# B2: 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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PI/Supervisor/signature and date of signing:

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Named Applicant, signature and date of signing:

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Named Applicant, signature and date of signing:

|  |  |
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### B3: Submission checklist

Please complete the following check list by answering YES, NO or N/A to each question

|  |  |
| --- | --- |
| 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 |  |
| All signatures have been included |  |

I confirm that I have checked the form and the related materials and addressed the ethical issues related to the proposed research.

I confirm that all named researchers have approved the final version of this submission;

Name (staff or supervisor)

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Signature (staff or supervisor)

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Date of signing

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The completed and signed form to be returned to ethicscommittee@leedstrinity.ac.uk