

**Faculty of Medicine and Health sciences Research Ethics Committee (fmhs FREC) Application Form**

# Instructions for completing this application form

This application form must be completed in full and submitted along with all project documents to apply for Keele University FMHS Faculty Research Ethics Committee review. Information on how to submit for FMHS FREC review can be found on the [FMHS FREC webpage](https://www.keele.ac.uk/research/raise/governanceintegrityandethics/researchethics/staffandpgrstudents/howtoapplyforkeeleuniversityrecreview/fmhsfrec/).

Where applicable, it is strongly advised that supervisors review and approve the application before it is submitted. Confirmation of this is required as part of the submission process.

Contents

[1 Instructions for completing this application form 1](#_Toc24452243)

[3 Project Details 3](#_Toc24452244)

[4 Aims, Objectives and Experimental Design 5](#_Toc24452245)

[5 Identification and Recruitment 6](#_Toc24452246)

[6 Participant Procedures 8](#_Toc24452247)

[7 Confidentiality and Data 9](#_Toc24452248)

[8 Further Information 10](#_Toc24452249)

# Project Details

All questions in this section are **mandatory** unless otherwise stated.

## Full Project title:

|  |
| --- |
| Click here to enter text. |

## Name of applicant:

|  |
| --- |
| Click here to enter text. |

## Name(s) of Keele Co-applicant(s):

|  |
| --- |
| Click here to enter text. |

## Academic unit:

|  |
| --- |
| Choose an item. |

## Proposed start date:

If you are unsure, please provide an estimate.

|  |
| --- |
| Click to enter a date. |

## Proposed end date:

If you are unsure, please provide an estimate.

|  |  |
| --- | --- |
| Click to enter a date. | Choose an item. |

## Status of funding:

Including internal sources.

|  |
| --- |
| Choose an item. |

## Funding references (where applicable):

|  |
| --- |
| Click here to enter a RaISE reference number if the project is seeking / has obtained external funding. |
| If there is external funding, is this provided by the Economic and Social Research Council ESRC? | Choose an item. |
| Click here to list any other funding references. |

## Please confirm that the project **DOES NOT** meet any of the following criteria that would require central research ethics committee (CREC) review.

|  |  |
| --- | --- |
| The research could expose participants to potential civil, criminal or other proceedings. (e.g. through disclosure of past events or prospective activity) | Choose an item. |
| Administering a substance to participants including drugs, nutritional supplements and challenge agents or other intrusive intervention e.g. hypnotherapy, transcranial magnetic stimulation. | Choose an item. |
| The research involves human exposure to ionising radiation / X-Ray. | Choose an item. |
| The research involves a risk of significant1 or permanent physical, mental or emotional harm, psychological stress, anxiety or humiliation requiring medical attention, treatment or other amelioration/mitigation/alleviation. | Choose an item. |
| The research involves prisoners and/or young offenders. | Choose an item. |
| The research involves participants without their consent in activity that will have a direct impact upon those participating. | Choose an item. |
| The research may bring the reputation of the University or other body into question (eg controversial sources of funding, engaging with issues that may cause offence to groups or individuals, or engaging in areas that might be misconstrued as endorsing illegal practices) | Choose an item. |
| The research could involve the generation of knowledge that could potentially be weaponisable. | Choose an item. |

1Significant is the threshold of harm that justifies compulsory intervention.

## Does the project involve the use of Security Sensitive Information?

See here for guidance on what constitutes [Security Sensitive Information](https://www.keele.ac.uk/research/raise/governanceintegrityandethics/securitysensitiveinformation/)

|  |
| --- |
| Choose an item. |

# Aims, Objectives and Experimental Design

All questions in this section are **mandatory** unless otherwise stated.

## Project synopsis:

Describe the purpose and rationale for the proposed project. The description should be in everyday language that is free from jargon. All technical terms, acronyms or discipline specific phrases must be clearly explained.

|  |
| --- |
| Click here to enter text. |

## Methodology:

Please give a brief description of the methodology of the project. This should not be a repetition of the study protocol.

|  |
| --- |
| Click here to enter text. |

## What are the primary outcome measures/aims?

|  |
| --- |
| Click here to enter text. |

## What are the secondary outcome measures/aims?

If there are no secondary outcome measures enter ‘Not applicable’.

|  |
| --- |
| Click here to enter text. |

## What is the significance or benefits of the project?

|  |
| --- |
| Click here to enter text. |

## Does the project involve Human Biomaterial?

This includes deceased persons, body parts or other human elements such as blood, hair or tissue samples (including saliva and waste products)?

|  |
| --- |
| Will human biomaterial be used? |
| If yes, give details with reference to the [Human Tissue Act 2004.](https://www.hta.gov.uk/policies/human-tissue-act-2004) |
| Click to enter details. |
| If yes, please discuss this project with Dr Alan Harper (01782 734654 (Med School) and 01782 674472 (Lab)) or Dr Daniel Tonge (01782 733418) or via email to research.humantissue@keele.ac.uk before submitting your application.  |
| *Insert the HTA reference number you are given for this project:* Click here to enter text. |

## Does the project involve any of the following?

|  |  |
| --- | --- |
| Personal Identifiable Information transferred into the University | Choose an item. |
| Personal Identifiable Information transferred out of the University | Choose an item. |
| Security Sensitive Information | Choose an item. |
| Ionising Radiation | Choose an item. |
| HRA approval (to be sought after REC approval) | Choose an item. |

# Identification and Recruitment

When submitting your application form you should also attach a copy of the Participant Information Sheet (if applicable), the Consent Form (if applicable), the content of any telephone script (if applicable) and any other material that will be used in the recruitment and consent process.

All questions in this section are **mandatory** unless otherwise stated.

## Describe the participant population:

Include relevant important characteristics such as age, gender, location, affiliation, level of fitness, intellectual ability etc. Describe any relevant inclusion/exclusion criteria.

|  |
| --- |
| Click here to enter text. |

## How many participants do you intend to recruit?

Describe per population group where applicable.

|  |
| --- |
| Click here to enter text. |

## From which source(s) do you plan to recruit your participants? E.g. schools, charitable organisations, universities, etc

|  |
| --- |
| Click here to enter text. |

## How will potential participants, records or samples be identified? Who will carry this out, what resources will be used?

|  |
| --- |
| Click here to enter text. |

## Will any of the following be used?

When submitting the application form a copy of each of these that are being used should be uploaded. For web content, insert a link below.

|  |  |
| --- | --- |
| Posters in public spaces | Choose an item. |
| Advertisements | Choose an item. |
| Emails | Choose an item. |
| Social Media | Choose an item. |
| Websites | Choose an item. |
| Click here to enter links to web content. |

## Describe what measures will be taken to ensure there is no breach of any duty of confidentiality owed to the public, service users or any other person in the process of identifying potential participants

|  |
| --- |
| Click here to enter text. |

## Will consent be obtained?

Describe how.

|  |
| --- |
| Will consent be obtained? |
| If yes, how will consent be obtained? If no, please explain why not |

## Will participants be deceived in any way about the purpose of the study?

If yes, please describe the nature and extent of the deception involved. Include how and when the deception will be revealed, why, and who will administer this feedback.

|  |
| --- |
| Will participants be deceived? |
| If yes, provide justification and details of how they will be deceived. |

## Describe how participants will be informed of and act upon their right to withdraw from the project:

|  |
| --- |
| Click here to enter text. |

## Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

|  |
| --- |
| Will participants be incentivised to take part? |
| If yes, describe how. |

## Will you inform participants of the results?

|  |
| --- |
| Choose an item. |
| Give details of how you will inform participants or justify if not doing so. |

# Participant Procedures

All questions in this section are **mandatory** unless otherwise stated.

## Give details of all procedure(s) that will be undergone by participants as part of the research protocol.

These include seeking consent, interviews, imaging investigations, taking samples of human biological material, observations and use of questionnaires.

For each procedure indicate:

* Total number of interventions/procedures to be received by each participant as part of the research protocol.
* If this intervention/procedure would be routinely given to participants outside the research, how many of the total would be routine?
* Average time taken per intervention/procedure (minutes, hours or days)
* Details of who will conduct the intervention/procedure, and where it will take place.

|  |
| --- |
| Click here to enter text. |

## What are the potential risks and burdens for research participants, the research team and the general public and how will you minimise them? What procedures will be adopted to manage adverse events should they occur?

|  |
| --- |
| Click here to enter text. |

## What are the potential risks to the environment and Society and how will you minimise them and what procedures will be adopted to manage adverse events?

|  |
| --- |
| Click here to enter text. |

## Are there any other ethical issues raised by the research?

|  |
| --- |
| Click here to enter text. |

# Confidentiality and Data

All questions in this section are **mandatory** unless otherwise stated.

## Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?

Check all that apply. Personal data is information that relates to an identified or identifiable individual. For guidance on what constitutes personal data see the [ICO Guidance](https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/key-definitions/what-is-personal-data/).

|  |  |
| --- | --- |
| Transferring personal data electronically or by hard copy, including by public/private transport, courier and postal services. | Choose an item. |
| Storing personal data on University Servers | Choose an item. |
| Storing personal data on University computers, laptops, digital devices, phones, tablets | Choose an item. |
| Storing personal data in University Premises | Choose an item. |
| Storing personal data on cloud services | Choose an item. |
| Storing personal data on private computers, laptops, digital devices, phones, tablets. | Choose an item. |
| Storing personal data on any form of removable storage media. | Choose an item. |

## Will participants be anonymous/rendered anonymous?

Please describe how data will be rendered de-identifiable/anonymous. See [ICO guidance](https://ico.org.uk/media/1061/anonymisation-code.pdf) (pdf).

|  |
| --- |
| Will participants be anonymous/rendered anonymous? |
| If yes, describe how. |

## Please describe the physical security arrangements for storage of personal data during the study?

|  |
| --- |
| Click here to enter text. |

## How will you ensure the confidentiality of personal data?

Consider data throughout the study lifespan and any publications/data sets made available.

|  |
| --- |
| Click here to enter text. |

## Where will research data be stored during the project’s activity?

|  |
| --- |
| Click here to enter text. |

## Describe the arrangements for storage of research data after the project has ended?

Please refer to the [University’s Record Retention Schedule](https://www.keele.ac.uk/recordsmanagement/recordsretentionschedule/) and the [Keele University Research Data Management and Sharing Policy](https://www.keele.ac.uk/informationgovernance/fortheuniversity/).

|  |
| --- |
| Click here to enter text. |

# Further Information

Once the REC Application Form is complete and all documentation is prepared and ready for submission, follow the process outlined on the [FMHS FREC Webpage](https://www.keele.ac.uk/research/raise/governanceintegrityandethics/researchethics/staffandpgrstudents/howtoapplyforkeeleuniversityrecreview/fmhsfrec/applyingtofmhsfrec/).