Research Ethics Committee (REC)

Application for ethical approval

**Please note:**

* This form has been created specifically for electronic completion using Microsoft Word 2013 on a PC. Some key features of this form may be incompatible with other software and Macs.
* **All items on this form require a response in order to allow the REC to scrutinise fully the research**. Incomplete applications may be returned to you, delaying the decision making process.
* Applicants should consult the [**EHU Ethics and Governance documents**](http://www.edgehill.ac.uk/research/research-ethics-governance/).
* Any ethical approval granted on the basis of this application ***covers only*** ***the original study specified in the application for this time period specified*** (unless advised otherwise by the relevant REC at the time of approval).
* If a study is extended or changed and/or further use of samples or data from a study already completed is required, **you must notify the REC** which granted your original approval.

Researcher details

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Lead researcher at EHU | | | | | | | |
|  | **Forename:** | | Click here to enter text. | | | | 1. **Surname:** | Click here to enter text. |
|  | Primary dept./ area: | FAS: | | Select dept./area. | | | | |
|  | FoE: | | Select dept./area. | | | | |
|  | FHSC: | | Select dept./area. | | | | |
|  | Other: | | Click here to enter text. | | | | |
|  | Is this application for a project in your capacity as EHU **staff** or EHU **student**? | | | | | Select your status. | | |
|  | *N.B. GTAs should always select ‘postgraduate student (PhD)’* | | | | | | | |
|  | Details if ‘*postgraduate student (other)*’: | | | | Click here to enter text. | | | |
|  | Names & affiliations of research team (inc. supervisors if applicant is a student) | | | | | | | |
| **6.** | Click here to enter text. | | | | | | | |

Project details

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Title: | | Click here to enter text. | | | | | | | | | | | | | | | | | | | | |
| 1. **[[1]](#footnote-1)** | **Start date:** | | | | | Click here to enter a date. | | | | | | | | | | | | 1. **End date:** | | | Click here to enter a date. | | |
|  | Source of funding: | | | | | | | | | | Click here to enter text. | | | | | | | | | | | | |
|  | Research method: | | | | | | | | | | Select a method. | | | | | | | | | | | | |
|  | Detail of other/ mixed methods: | | | | | | | | | Click here to enter text. | | | | | | | | | | | | | |
|  | Risk assessment | | | | | | | | | | | | | | | | | | | | | | |
|  | Have you read and considered the [**guidance on Research Risk Assessment at EHU *(RO-GOV-06)***](https://www.edgehill.ac.uk/research/files/2012/05/Research-Strategy-Policies-and-Codes-Research-Risk-Assessment-Guidance-RO-GOV-06.pdf) and addressed any matters arising from this? | | | | | | | | | | | | | | | | | | | | | | |
|  | **Yes** | | |  | | | **No** | | | | | | |  | | | | | | | | | |
|  | What are the key risks associated with your proposal? | | | | | | | | | | | | | | | | | | | Click here to enter text. | | | |
|  | How do you plan to mitigate these? | | | | | | | | | | | | | | | | | | | Click here to enter text. | | | |
|  | Data collection & research methods | | | | | | | | | | | | | | | | | | | | | | |
|  | Does this research involve human tissue? | | | | | | | | | | | | | | | | | | | | | | |
|  | **Yes** | | |  | | | **No** | | | | | | |  | | | | | | | | | |
| **15.1** |  | ***If yes***, does this activity fall under the University’s Human Tissue Authority (HTA) licence?**[[2]](#footnote-2)** | | | | | | | | | | | | | | | | | | | | | |
|  | **Yes** | | | | | | | |  | | | **No** | | |  | | | | | | | | |
|  | Does this research fall under the Nagoya Protocol?[[3]](#footnote-3)   |  |  |  |  | | --- | --- | --- | --- | | **Yes** |  | **No** |  | | | | | | | | | | | | | | | | | | | | | | | |
|  | Does this research require working with sensitive materials?[[4]](#footnote-4)   |  |  |  |  | | --- | --- | --- | --- | | **Yes** |  | **No** |  | | | | | | | | | | | | | | | | | | | | | | | |
|  | Do your data collection and research methods include any of the following? Please tick all that apply. | | | | | | | | | | | | | | | | | | | | | | |
|  | *Non-invasive* | | | | | | | | | | | | | | |  | | | *Collection of other bodily tissues, secretions or excretions* | | |  |
|  | *Administering drugs or other substances* | | | | | | | | | | | | | | |  | | | *Deception (excluding blind research design)* | | |  |
|  | *Blood sample (via needle insertion)* | | | | | | | | | | | | | | |  | | | *Use of distressing images, video or other media* | | |  |
|  | *Blood sample (not via needle insertion)* | | | | | | | | | | | | | | |  | | | *Other physically or psychologically invasive method* | | |  |
|  | Please provide brief details of the research method(s) and use of human tissue: | | | | | | | | | | | | | | | | Click here to enter text. | | | | | | |
|  | Location of project: | | | | | | | | | | | | Select location. | | | | | | | | | | |
|  | Detail if other location: | | | | | | | | | | | | Click here to enter text. | | | | | | | | | | |
|  | Could the location present any risks to either the researcher(s) or to third parties (e.g. the general public, research subjects, etc.)? | | | | | | | | | | | | | | | | | | | | | | |
|  | **Yes** | | | |  | | | **No** | | | | |  | | | | | | | | | | |
|  | Please provide brief details: | | | | | | | | | | | | | | | | Click here to enter text. | | | | | | |
|  | Research subjects: | | | | | | | | | | | | | | | | Select research subjects. | | | | | | |
|  | Detail if other subjects: | | | | | | | | | | | | | | | | Click here to enter text. | | | | | | |
|  | If you are working with children or vulnerable adults, please indicate whether you have Disclosure and Barring Service clearance.   |  |  |  |  | | --- | --- | --- | --- | | **Yes** |  | **No** |  | | | | | | | | | | | | | | | | | | | | | | | |

Ethical approval information

*Please attach separate sheet(s) for this section if necessary*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Has this proposal been through **external or parallel** ethical approval processes? | | | | |
|  | **Yes** |  | **No** |  | | |
|  | Details: | Click here to enter text. | | |
|  | Is this health related research?   |  |  |  |  | | --- | --- | --- | --- | | **Yes** |  | **No** |  | | | | | |
| **29.1** | ***If Yes*** is the University acting as sponsor?   |  |  |  |  | | --- | --- | --- | --- | | **Yes** |  | **No** |  | | | | | |
|  | Is this proposal an **extension** of a project that has **previously** undergone ethical approval procedures? | | | | |
|  | **Yes** |  | **No** |  | | |
|  | Details (including any reference numbers) : | | | Click here to enter text. |
|  | Does this proposal require a specific ethical approval action (e.g. letter, facility) to be produced to support the project? | | | | |
|  | **Yes** |  | **No** |  | | |
|  | Details: | Click here to enter text. | | |

Outline of the Project & Ethical Issues

**Please attach your research proposal.**

Proposals should include details under the categories listed below. They can be presented in a submission written specifically for this document or consist of other written documents that outline the project (e.g. to external funders), as long as a cover sheet clearly specifies upon where each of the categories listed are elaborated.

Submissions should include such detail as to allow readers to gain a clear understanding of the applicants’ attention to ethical issues and problems.

|  |  |
| --- | --- |
| Categories | |
|  | Title of project/aims and objective of the project |
|  | Outline of the project |
|  | Methodology and outline of methods and analysis |
|  | Identification of research participants |
|  | Timescales and staging of the project |
|  | Budget and logistics/sources of funding |
|  | Specific ethical considerations/risk assessment |
|  | Relevant supporting documents (e.g. consent forms, information sheets, invitation letters) |
|  | Confirmation that EHU policies & procedures have been followed (e.g. risk assessment, health & safety protocol) |
|  | Processes by which ethical review will be in place throughout the project |
|  | Details of research staff |

|  |  |
| --- | --- |
| Applicant signature  *(Lead researcher if part of a research team)* | EHU Designated Individual signature  *(Only activity involving human tissue)* |

▼***Please insert or type your signature in the relevant box below*** ▼

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

|  |  |
| --- | --- |
| Date: Click here to enter a date. | Date: Click here to enter a date. |

**Please obtain support from your Head of Department/Area before submitting this form to the appropriate REC contact (see below).**

Head of Department/Area supporting statement

**The Head of Department/Area (HoD) should be satisfied that the application for ethical approval is of an appropriate standard and that suitable controls have been introduced by the researcher(s) for health and safety, risk assessment and other governance issues.**

N.B. if the applicant is a HoD, this supporting statement should come from his/her line manager.

|  |  |
| --- | --- |
| Supporting statement | |
| Click here to enter text. | |
| HoD name: | Click here to enter text. |

HoD signature

Please insert or type your signature in the box below

|  |
| --- |
|  |

Date: Click here to enter a date.

|  |  |
| --- | --- |
| **Your completed, signed form should be returned to:** | |
| **FAS:** | Faculty Research Ethics Committee (FREC) Secretary ([Ruth Carr](mailto:Carrr@edgehill.ac.uk)) |
| **FHSC:** | Faculty Research Ethics Committee (FREC) Secretary ([Daniel Brown](mailto:Daniel.Brown@edgehill.ac.uk)) |
| **FoE:** | Faculty Research Ethics Committee (FREC) Secretary ([Julie Kirby](mailto:Kirbyjul@edgehill.ac.uk)) |

DREC/FREC Decision

**The DREC/FREC responsible for scrutinising this application should ensure the applicant’s Head of Department (or Research Degree Supervisor) is made aware of the application and its progress.**

|  |  |
| --- | --- |
| Comments from DREC/FREC Chair | |
| Click here to enter text. | |
| Chair name: | Click here to enter text. |

DREC/FREC Chair signature

Please insert or type your signature in the box below

|  |
| --- |
|  |

Date: Click here to enter a date.

DREC/FREC decision

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Is the following decision that of **DREC** or **FREC**? | | | Select relevant REC. | |
| Approved |  | Application reference: | | Click here to enter text. |
| Re-submit to this DREC/FREC |  | Minute reference: | | Click here to enter text. |
| Re-submit for chair’s action |  | DREC/FREC date: | | Click here to enter a date. |
| Refer to FREC |  | Decision date: | | Click here to enter a date. |
| Refer to URESC |  | Further action where needed: | | Click here to enter text. |
| Rejected |  |

***Please note:*** *if rejected, the applicant has the right to lodge an appeal with URESC as per the* [***Framework for Research Ethics (RO-GOV-03)***](https://www.edgehill.ac.uk/research/files/2012/05/Ethics-Output-Background-Framework-for-Research-Ethics-RO-GOV-03.pdf)

URESC decision (where applicable)

|  |  |
| --- | --- |
| Comments from URESC Chair | |
| Click here to enter text. | |
| Chair name: | Click here to enter text. |

URESC Chair signature

Please insert or type your signature in the box below

|  |
| --- |
|  |

Date: Click here to enter a date.

URESC decision

|  |  |  |  |
| --- | --- | --- | --- |
| Approved |  | Application reference: | Click here to enter text. |
| Re-submit to DREC |  | Minute reference: | Click here to enter text. |
| Re-submit to FREC |  | URESC date: | Click here to enter a date. |
| Re-submit to URESC |  | Decision date: | Click here to enter a date. |
| Rejected |  | Further action where needed: | Click here to enter text. |

*Document updated November 2017*

1. The project start and end dates in questions 8 and 9 respectively refer to the element of your research requiring ethical approval, such as, but not limited to the period in which you are seeking consent from participants and the period of data collection. If you are in doubt, please seek advice. [↑](#footnote-ref-1)
2. Please refer to the EHU HTA web pages -[https://www.edgehill.ac.uk/research/human-tissue](https://www.edgehill.ac.uk/research/human-tissue/)/ you will also need to obtain the signature of the University’s HTA licence Designated Individual at the end of this form. [↑](#footnote-ref-2)
3. The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity (CBD) is a supplementary agreement to the Convention on Biological Diversity: It applies to genetic resources that are covered by the CBD. Please refer to the University’s [Research Ethics Policy](https://www.edgehill.ac.uk/research/files/2017/11/Ethics-Research-Ethics-Policy-RO-GOV-03.pdf) [↑](#footnote-ref-3)
4. Research involving access to highly sensitive materials including access to the ‘dark web’, security-related materials, and other materials of a distressing or sensitive nature are subject to special arrangements: Please refer to the University’s [Research Ethics Policy](https://www.edgehill.ac.uk/research/files/2017/11/Ethics-Research-Ethics-Policy-RO-GOV-03.pdf) [↑](#footnote-ref-4)