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**Form RE2(U)**

**University Ethics Committee (UREC)**

September 2021

University Application For Ethics Approval Of A Research Project/Teaching Activity

**EFIT Case Reference Number:** *(where EFIT was used initially)*

**This application form is to be used when seeking approval from the University Ethics Committee following a request for ethical clearance via an RE1 or submission to EFIT.**

***Applicants must go through School/Centre procedures and the School/Centre Research Ethics Officer must sign off the application.***

***Ethics approval must be obtained before potential participants are approached to take part in any research/teaching activity.***

**Note:** Your research project/teaching activity must not proceed until written approval has been received from UREC.



**Applicant Details**

|  |  |
| --- | --- |
| Name |  |
| Status *(please click to select)*: | Choose an item. |
| Programme of Study: |  |
| Email Address: |  |
| Contact Address: |  |
| Telephone Number: |  |

**Project/Teaching Activity Details**

|  |  |
| --- | --- |
| Title: |  |
| Brief description of the project/activity: | |
|  | |

**Contextual Information:**

|  |  |
| --- | --- |
| Course title/module name/number:  *(where application is for teaching activity)* |  |
| School/Centre: |  |
| Supervisor / Module Leader name: |  |
| Email address: |  |
| Telephone: |  |

**Declaration by Applicant**

The information contained herein is, to the best of my knowledge and belief, accurate. I have read the University’s Code of Practice for Ethical Standards, and accept responsibility for the conduct of the procedures set out in the attached application in accordance with the guidelines, the University’s Code of Practice and any other condition laid down by the University’s Ethics Committee (UREC). I have attempted to identify all risks related to the research that may arise in conducting this research and acknowledge my obligations and the rights of the participants.

I have the appropriate qualifications, experience and facilities to conduct the research set out in the attached application and to deal with any emergencies and contingencies related to the research that may arise.

**Signature of Applicant:**

**Date:**

# Declaration By School/Centre Research Ethics Officer

*I have / the Departmental Research Ethics Committee has (delete as appropriate) reviewed this project and considers the methodological/technical and ethical aspects of the proposal to be appropriate to the tasks proposed and recommends approval of the project/ teaching activity.*

Stipulations *(if any)*:

**Signature of REO:**

**Date:**

# University Ethics Committee (UREC) Use Only

|  |  |
| --- | --- |
| Date application received *(Secretary)* |  |

|  |  |
| --- | --- |
| Date of meeting: |  |

**Decision:**

**Note:** Where the RE2(U) has been requested through the EFIT system then the decision will be communicated through that system and a certificate issued outlining the approval/non-approval.

|  |  |
| --- | --- |
|  | Tick ONE Box |
| Approved |  |
| *Approved subject to specific conditions* |  |
| Not approved |  |
| *Returned for further clarification* |  |

**1. Project Details**

# 1.2 Lay Description: Provide a brief outline of the project/activity, including what participants will be required to do or what human tissues will be used. This description must be in everyday language which is free from jargon. Please explain any technical terms or discipline-specific phrases. (No more than 350 words)

# 1.3 Aims Of And Justification For The Research: State the aims and significance of the project/ activity. Where relevant, state the specific hypothesis to be tested. Also please provide a brief description of the proposed research, a justification as to why this research/activity should proceed and an explanation of any expected benefits to the community. Please provide full references for any work referred to. (No more than 700 words)

**1.4 Proposed Method:** *Provide an outline of the proposed method, including details of data collection techniques, tasks participants will be asked to do, the estimated time commitment involved, and how data will be analysed. If the project includes any procedure which is beyond already established and accepted techniques please include a description of it. For human tissues explain how these will be collected, used and disposed. (No more than 500 words.)*

**1.5 Applicant’s Qualifications, Experience And Skills**

*List the academic qualifications and outline the experience and skills relevant to this project that the researchers and any supporting staff have in carrying out the research and in dealing with any emergencies, unexpected outcomes, or contingencies that may arise.*

1.6 For research projects: please explain when, how, where, and to whom results will be disseminated, including whether participants will be provided with any information on the findings or outcomes of the project

**1.7 Will The Research Be Undertaken *Only* On-Site At The University Of Bolton (Including All Campuses)?**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **YES** only on-site |  | **NO** |  | *(If* ***NO****, give details of off-campus location)* |

**1.8 Other Approvals Required:** *Has permission to conduct the research in, at or through another institution or organisation (eg a School) been obtained? Individuals proposing to conduct research involving contact with children or vulnerable adults must first get agreement from the individual with appropriate authority in the institution or organization through which the research is being conducted. (Copies of letters of approval to be provided with this form)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **YES** |  | **NO** |  | **NOT APPLICABLE** |  |

*(If YES, please specify from whom and attach a copy. If NO, please explain when this will be obtained.)*

**1.9 Is This Protocol Being Submitted To Another Ethics Committee, Or Has It Been Previously Submitted To An Ethics Committee?** *This includes an NHS Local Research Ethics Committee or any other institutional committee of collaborating partners or research sites.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **YES** |  | *(If YES, please provide details including correspondence setting out conditions of approval.)* | **NO** |  |

# 2. Participant Details

# 2.1 Do You Intend To Recruit: (Tick as many as applicable)

|  |  |
| --- | --- |
|  | **YES/NO** |
| a) students or staff of this University (i.e. recruitment on-site at Bolton) | Choose an item. |
| b) adults (over the age of 16 years and competent to give consent) | Choose an item. |
| c) children/legal minors (anyone under the age of 16 years) | Choose an item. |
| d) patients or clients of professionals | Choose an item. |
| e) anyone who is in custody, custodial care, or for whom a court have assumed  responsibility | Choose an item. |
| f) any other person whose capacity to consent may be compromised | Choose an item. |
| g) a member of an organisation where another individual may also need to give consent | Choose an item. |

2.2 Number, Age Range And Source Of Participants

*Provide number, age range and source of participants. Please provide an explanation for your proposed sample size (including details of statistical power of the sample, where appropriate) and state any exclusion or inclusion criteria.*

2.3 Means By Which Participants Are To Be Recruited

*Please provide specific details of how you will be recruiting participants. How will people be told you are doing this research?  How will they be approached and asked if they are willing to participate?  If you are mailing to or phoning people, please explain how you have obtained or will obtain their names and contact details. This information will need to be included in the participant information sheet. If a recruitment advertisement is to be used, please ensure you attach a copy to this application.*

2.4 Will Parts Of This Project Be Carried Out By Independent Contractors?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **YES** |  | *(If YES, please explain who the independent contractors are, what their role will be and how their work will be monitored. Responsibility for proper conduct of the project remains with the Principal Investigator)* | **NO** |  |

2.5 Are Any Of The Participants In A Dependent Relationship With Any Of The Investigators, Particularly Those Involved In Recruiting For Or Conducting The Project?

Research involving persons in dependent or unequal relationships (for instance, teacher/student) may compromise a participant’s ability to give consent which is free from any form of pressure (real or implied) arising from this unequal power relationship. It is therefore recommended that, where possible, researchers choose participant cohorts where no dependent relationship exists. If, after due consideration, the investigator believes that research involving people in dependent relationships is purposeful and defensible, then the University Research Ethics Committee will require additional information setting out the case and detailing how risks inherent in the dependent relationship will be managed. The Committee will also need to be reassured that refusal to participate will not result in any discrimination or penalty.

NB. Reasons of convenience alone will not normally be considered adequate justification for conducting research in situations where dependent relationships exist.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **YES** |  | *(If YES, please explain the relationship (eg. teacher/student, student/lecturer, doctor/patient, employer/employee) and the steps to be taken by the investigators to ensure that the participant’s participation is purely voluntary and not influenced by the relationship in any way)* | **NO** |  |

# 2.6 Payment Or Incentives: Do You Propose To Pay Or Reward Participants?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **YES** |  | *(If YES, how, how much and for what purpose?)* | **NO** |  |

# 3. Risk And Risk Management

**3.1 Does The Research or Teaching Activity Involve:**

|  |  |
| --- | --- |
|  | **YES/NO** |
| 1. use of a questionnaire or similar research instrument or measure? (attach copy) | Choose an item. |
| 1. use of written or computerised tests | Choose an item. |
| 1. interviews? (attach interview questions) | Choose an item. |
| 1. diaries? (attach diary record form) | Choose an item. |
| 1. participant observation? | Choose an item. |
| 1. observation of participants (in a non-public place) without their knowledge? | Choose an item. |
| 1. Audio recording interviewees or events? | Choose an item. |
| 1. Video recording interviewees or events? | Choose an item. |
| 1. access to personal and/or confidential data? (including student, patient or client data) without the participant’s specific consent | Choose an item. |
| 1. administration of any questions, tasks, investigations, procedures or stimuli which may be experienced by participants as physically or mentally painful, stressful or unpleasant during or after the research process? | Choose an item. |
| 1. performance of any acts which might diminish the self-esteem of participants or cause them to experience embarrassment, regret or depression? | Choose an item. |
| 1. investigation of participants involved in illegal activities? | Choose an item. |
| 1. procedures that involve deception of participants? | Choose an item. |
| 1. administration of any substance or agent? | Choose an item. |
| 1. use of non-treatment of placebo control conditions? | Choose an item. |
| 1. participation in a clinical trial? | Choose an item. |
| 1. administration of ionising radiation to participants? | Choose an item. |
| 1. research overseas? | Choose an item. |
| 1. the potential to uncover or highlight potential illegal or harmful activities? | Choose an item. |
| 1. the discussion of topics which the participants may find sensitive or disturbing (e.g. sexual activity, drug use, controversial/extreme texts)? | Choose an item. |
| 1. socially or politically sensitive (actual or potential) topics? | Choose an item. |
| 1. any potential implications for the reputation of the university? | Choose an item. |

# 3.2 Potential Risk To Participants, Researchers And The University And Risk Management Procedures That Will Be Implemented

*Identify, as far as possible, all potential risks to participants, researchers and the University. Where you have answered YES to any item in 3 you MUST explain what risk management procedures will be put in place in each case by way of mitigation.*

3.3 Are There Any Specific Risks To Researchers That Are Greater Than Those Encountered In Normal Day To Day Life?

*(Where research is undertaken at an off-campus location, UK or abroad, researchers should consult the relevant University guidelines regarding risk assessment and seek the advice of the University’s Health and Safety Advisor. The Head of School/Centre has overall responsibility for risk assessment regarding the health and safety of researchers. Useful advice for the safety of researchers is available on the Social Research Association website at:* [*https://the-sra.org.uk/common/Uploaded%20files/SRA-safety-code-of-practice.pdf*](https://the-sra.org.uk/common/Uploaded%20files/SRA-safety-code-of-practice.pdf)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **YES** |  | *(If YES, please describe)* | **NO** |  |

3.4 Please Explain How The Potential Benefits Of The Research Outweigh Any Risks To Participants*. Briefly describe the main benefits and contribution of the study. Include any immediate benefits to participants as well as the overall contribution to knowledge or practice.*

**3.5 Adverse / Unexpected Outcomes**

*Please describe what measures you have in place in the event of any unexpected outcomes or adverse effects to participants arising from involvement in the project.*

**3.6 Debriefing, Support and/or Feedback To Participants (As Appropriate)**

*What, if any, debriefing, support or feedback will participants receive following the study and when? Participants may need to talk about the experience of being involved in the study or about issues it has raised for them. Depending on risks to participants you may need to consider having additional support for participants during/after the study (e.g., external counseling). Further information on the aims of the research, their own performance and/or the results of the study may also be appropriate.*

3.8 Monitoring

*Please explain how the researchers propose to monitor the conduct of the project (especially where several people are involved in recruiting or interviewing, administering procedures) to ensure that it conforms with the procedures set out in this application, the University’s Code of Practice and any guidelines published by their relevant PSRB.*

# 4. Human Tissues And Material

* 1. The definition of Human Tissues and Material is laid down in the Human Tissue Act 2004 and is complex. The Human Tissue Authority have produced a series of Codes of Practice available at <https://www.hta.gov.uk/guidance-professionals/codes-practice>

I confirm that have read the appropriate Code(s) of Practice for the work for which I am seeking ethical clearance;

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **YES** |  | *Please state which Codes you have read* | **NO** |  | *(If* ***NO****, please explain why)* |

* 1. The University does not hold an HTA licence but there are exemptions for working with certain materials; <https://www.bolton.ac.uk/assets/Registration-and-Storage-of-Human-Tissue-for-the-Purpose-of-Research-Nov-2017.pdf>

Does the proposed work fall under one or more of the exemption categories?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **YES** |  | *Explain which exemption applies and why it covers your work* | **NO** |  |

* 1. Have you discussed the use of UmanHumanHHuman Tissues with the relevant Research Ethics Officer REO)?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **YES** |  | *REO name:*  *Date of discussion:*  *Outline the key outcomes from your discussion* | **NO** |  |

* 1. Have You Received Ethcial Clearance Form An HTA-Approved National Ethics Body?

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **YES** |  | *Please attach a copy of the clearance to this application* |  | **NO** |  | *(If* ***NO****, please explain why)* |

# 5. Informed Consent

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **YES** |  | **NO** |  | *(If* ***NO****, please explain)* |

* 1. Have You Attached To Your Application A Copy Of The Participant Information Sheet?  *(Guidelines for drafting this are provided on the research ethics web page(s). The sample Participant Information Sheet can be found at* [*https://www.bolton.ac.uk/assets/Uploads/Example-1-Participant-Info-Sheet-April-2018.pdf*](https://www.bolton.ac.uk/assets/Uploads/Example-1-Participant-Info-Sheet-April-2018.pdf)

*University letterhead should be used for information and informed consent documents.)*

* 1. Have You Attached To Your Application A Copy Of The Informed Consent Form? - *if you are not obtaining consent in writing please explain how the informed consent process is to be documented. (Guidelines for drafting a consent form are provided on the research ethics web page a sample Informed Consent Agreement can be found at* [*https://www.bolton.ac.uk/assets/Uploads/Example-2-Consent-Form-April-2018.pdf*](https://www.bolton.ac.uk/assets/Uploads/Example-2-Consent-Form-April-2018.pdf) *University of Bolton letterhead should be used for consent forms.)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **YES** |  | **NO** |  | *(If* ***NO****, please explain)* |

# 6. Confidentiality/Anonymity

* 1. Will the research/activity involve:

|  |  |
| --- | --- |
|  | **YES/NO** |
| 1. complete anonymity of participants (i.e., researchers will not know the identity of participants as participants are part of a random sample and are required to return responses with no form of personal identification)? | Choose an item. |
| 1. anonymised samples or data (i.e., an irreversible process whereby identifiers are removed from data and replaced by a code, with no record retained of how the code relates to the identifiers. It is then impossible to identify the individual to whom the sample of information relates)? | Choose an item. |
| 1. de-identified samples or data (i.e., a reversible process in which the identifiers are removed and replaced by a code. Those handling the data subsequently do so using the code. If necessary, it is possible to link the code to the original identifiers and identify the individual to whom the sample or information relates)? | Choose an item. |
| 1. participants having the option of being identified in any publication arising from the research? | Choose an item. |
| 1. participants being referred to by pseudonym in any publication arising from the research? | Choose an item. |

* the use of personal data?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **YES** |  | *(If YES, you must check the data protection policies at:* [*https://www.bolton.ac.uk/governance/documents-and-reports/#dataprotection/*](https://www.bolton.ac.uk/governance/documents-and-reports/#dataprotection/) *and discuss this with your REO and explain how you will comply with the requirements of the policies)* | **NO** |  |

*Please bear in mind that where the sample size is very small, it may be impossible to guarantee anonymity/confidentiality of participant identity. Participants involved in such projects need to be advised of this limitation.*

# Which Of The Following Methods Of Assuring Confidentiality Of Data Will Be Implemented? Please select all relevant options.

|  |  |
| --- | --- |
| 1. data and codes and all identifying information to be kept in separate locked cabinets |  |
| 1. access to computer files to be available by password only |  |
| 1. other *(please describe)* |  |

* 1. Legal Limitations To Data Confidentiality: *Participants need to be aware that the confidentiality* *of the information they provide can only be protected within the limitations of the law - i.e. it is possible for data to be subject to subpoena, freedom of information claim or mandated reporting by some professions. This only applies to named or de-identified data. If your participants are named or de-identified, you may need to specifically state these limitations. You must check the data protection policies at:* [*https://www.bolton.ac.uk/governance/documents-and-reports/#dataprotection/*](https://www.bolton.ac.uk/governance/documents-and-reports/#dataprotection/) *and discuss this with your REO and explain how you will comply with the requirements of the policies*

Will your participants be made aware of these limitations?

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **YES** |  | *Please explain how they will be made aware;* | **NO** |  | *(If* ***NO****, please explain why not)* |

# 7. Data Access, Storage And Security

* 1. Will Data Be Generated As A Result Of This Research/Activity?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **YES** |  | **NO** |  | *If NO then go to Section 8* |

* 1. Will You Be Responsible for the Security of Data Collected?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **YES** |  | **NO** |  | *(If* ***NO****, please explain who will be responsible)* |

* 1. Who Will Have Access To The Data?

|  |  |
| --- | --- |
|  | Access by named researchers only |
|  | Access by people other than you  *(Please explain:)* |

* 1. Where Will The Data be stored?

|  |  |
| --- | --- |
|  | Stored at the University of Bolton |
|  | Stored at another site  *(Please explain where and for what purpose:)* |

* 1. Does Data Storage Comply With The University’s Guidelines For The Management Of Research Data And Records? *Please refer to* [*https://www.bolton.ac.uk/assets/Item-5-RDM-1-Data-Management-Plan-Guidelines.pdf*](https://www.bolton.ac.uk/assets/Item-5-RDM-1-Data-Management-Plan-Guidelines.pdf)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **YES** |  | **NO** |  | *(If* ***NO****, please explain why)* |

# 8. Funding

* 1. Is This Project/Activity Being Funded?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **YES** |  | **NO** |  | *(If* ***NO****, please go to section 9)* |

* 1. Specify The Source Of Funding?
  2. Project Grant Title And Proposed Duration Of Grant *(Where applicable)*

* 1. Does The Project Require Ethical Approval Before Consideration By A Funding Agency?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **YES** |  | *Funding Agency Deadline?* | **NO** |  |

* 1. **How Will Participants Be Informed Of The Source Of The Funding?** *The source of funding should normally be explained in the participant information sheet.*

# 9. CHECKLIST

Please check that the following documents are submitted with your application.

|  |  |
| --- | --- |
|  | Attached/Not Applicable |
| Recruitment advertisement (question 2.3) | Choose an item. |
| Participant information sheet (question 5.1) | Choose an item. |
| Consent form (question 5.2) | Choose an item. |
| Evidence of external approvals related to the research (question 1.9) | Choose an item. |
| Questionnaire (question 3.1) | Choose an item. |
| Interview Schedule (question 3.1) | Choose an item. |
| HTA national ethics body approval (question 4.4) | Choose an item. |
| NHS approval (question 1.9) | Choose an item. |
| Other (*please specify: )* | Choose an item. |

|  |
| --- |
| For further details about completion of this form, please contact your School/Centre Research Ethics Officer in the first instance. |