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**Form RE2(U)**

**University Research Ethics Committee**

June 2017

University Application For Approval Of A Project Involving Human Participants, Data Or Material

**Registration No.** *(office use only)*

**Period of Approval** *(office use only)**....../....../......*to *....../....../......  
Approval is for two years from the date the full approval letter was issued or six months after the study is due to be completed, whichever is longest.*

**This application form is to be used by researchers seeking approval from the University Research Ethics Committee.** *Applications must be completed on the form****; ANSWERS IN THE FORM OF ATTACHMENTS WILL NOT BE ACCEPTED, EXCEPT WHERE INDICATED****.* ***No handwritten applications will be accepted****. Applicants should contact the appropriate School/Centre Research Ethics Officer to establish procedures for research ethics review in the School/Centre.* ***Applicants must go through School/Centre procedures and the School/Centre Research Ethics Officer must sign off the application before it is copied and submitted to the Secretary for the University Research Ethics Committee.***

When the School/Centre Research Ethics Officer has signed the application, please submit the completed application to the Secretary to the University Research Ethics Committee, Quality Assurance and Enhancement, Services & Administration Centre, Eagle. Only those applications received two weeks prior to the next meeting will be considered. Alternatively, multiple copies of the application may be submitted to the Secretary up to 11 days prior to the meeting.

**Potential participants must not be contacted until written approval has been received from the Committee.**

|  |  |
| --- | --- |
| **PROJECT TITLE:** |  |
| **START DATE:** | **/****/****END DATE:** **/****/** |

|  |  |  |
| --- | --- | --- |
| **THIS PROJECT IS:** |  | Staff Research Project |
| *(tick as many as apply)* |  | Research Student Project |
|  |  | Project by External Researcher  *(please give details)* |
|  |  | Project by member of staff from another institution  (*please give details of Post and Institution, including address)* |
|  |  | MPhil/PhD student from another institution  (*please give details of Department and Institution, including address)* |
|  |  | Masters student from another institution  (*please give details of Department and Institution, including address)* |
|  |  | Class Research  (please give details of the programme, module and year) |

**PRINCIPAL INVESTIGATOR(S):** *Research students can be listed as Principal Investigator after their supervisors. The Director of Studies should also be identified.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| *TITLE & NAME* | *POST* | *DEPARTMENT* | *PHONE* | *EMAIL* |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**OTHER INVESTIGATORS:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| *TITLE & NAME* | *POST* | | *DEPARTMENT* | *PHONE* | *EMAIL* |
|  |  | |  |  |  |
|  |  | |  |  |  |
|  |  | |  |  |  |
|  |  | |  |  |  |
| **ADDRESS FOR CORRESPONDENCE (PRINCIPAL INVESTIGATOR):** | |  | | | |

**DECLARATION BY INVESTIGATORS**

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 for Research Involving Human Participants, 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 Research Ethics Committee. 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 and my co-investigators or supporting staff 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(s)* |  | *Date* | */**/* |
| *Principal Investigator(s)* | |  |  |
|  |  |  |  |
| Print name(s) of Principal Investigator(s) in block letters | |  |  |

# Declaration By Departmental Research Ethics Officer

|  |  |  |
| --- | --- | --- |
| Date application received: | /     / |  |

|  |  |
| --- | --- |
| *DATE ETHICS REVIEW COMPLETED* | /     / |

*The Departmental Research Ethics Committee has 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. The Departmental Research Ethics Committee considers that the investigator(s) has/have the necessary qualifications, experience and facilities to conduct the research set out in the attached application, and to deal with any emergencies and contingencies that may arise.*

Comments/Provisos:           

The project meets the criteria of minimal risk and chair’s action is recommended (delete if inapplicable)

|  |  |  |  |
| --- | --- | --- | --- |
| *Signature:* |  | *Date* | */**/* |
| Print name in block letters | |  |  |

# university research ethics COMMITTEE USE ONLY

|  |  |
| --- | --- |
| *Date application received:* | */     /* |

|  |  |
| --- | --- |
| *Date discussed:* | */     /* |

***Decision:***

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| *Date:* | */     /* | *Approved* |  | *Approved,*  *subject to specific conditions* | |  | *Not approved* |  | *Returned for further clarification* |  |
|  |  |  |  |  | |  |  |  |  |  |
| *Date:* | */     /* | *Approved* |  | *Approved,*  *subject to specific conditions* | |  | *Not approved* |  | *Returned for further clarification* |  |
|  |  |  |  |  | |  |  |  |  |  |
| *Date:* | */     /* | *Approved* |  | *Approved,*  *subject to specific conditions* | |  | *Not approved* |  | *Returned for further clarification* |  |
| Date of final approval | | */     /* | | |

**1. PROJECT DETAILS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1.1 | PROPOSED DURATION OF DATACOLLECTION COMPONENT OF PROJECT | From: | /     / | To: | /     / |
|  |  |  |  |  |  |

# 1.2 LAY DESCRIPTION: Provide a brief outline of the project, including what participants will be required to do. 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. 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 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. (No more than 500 words.)*

**1.5 INVESTIGATORS’ 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 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, not only on-site | *(If NO, give details of off-campus location, including other sites where research is being undertaken and other countries providing data.)* |

**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)*

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

# 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) |  |  |
| b) adults (over the age of 16 years and competent to give consent) |  |  |
| c) children/legal minors (anyone under the age of 16 years) |  |  |
| d) patients or clients of professionals |  |  |
| e) anyone who is in custody, custodial care, or for whom a court have assumed responsibility |  |  |
| f) any other person whose capacity to consent may be compromised |  |  |
| g) a member of an organisation where another individual may also need to give consent |  |  |

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 |  | NO | 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.] | |
|  |  | | | |

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 |  | NO | *(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.)* | |
|  |  | | | |

# 2.6 PAYMENT OR INCENTIVES: Do you propose to pay or reward participants?

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

# 3. RISK AND RISK MANAGEMENT

**3.1 DOES THE RESEARCH INVOLVE:**

|  |  |  |
| --- | --- | --- |
|  | **YES** | **NO** |
| 1. use of a questionnaire or similar research instrument or measure? (attach copy) |  |  |
| 1. use of written or computerised tests |  |  |
| 1. interviews? (attach interview questions) |  |  |
| 1. diaries? (attach diary record form) |  |  |
| 1. participant observation? |  |  |
| 1. observation of participants (in a non-public place) without their knowledge? |  |  |
| 1. audio-taping interviewees or events? |  |  |
| 1. video-taping interviewees or events? |  |  |
| 1. access to personal and/or confidential data? (including student, patient or client data) without the participant’s specific consent |  |  |
| 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? |  |  |
| 1. performance of any acts which might diminish the self-esteem of participants or cause them to experience embarrassment, regret or depression? |  |  |
| 1. investigation of participants involved in illegal activities? |  |  |
| 1. procedures that involve deception of participants? |  |  |
| 1. administration of any substance or agent? |  |  |
| 1. use of non-treatment of placebo control conditions? |  |  |
| 1. collection of body tissues or fluid samples? |  |  |
| 1. collection and/or testing of DNA samples? |  |  |
| 1. collection and/or testing of gametes or embryo tissue? |  |  |
| 1. participation in a clinical trial? |  |  |
| 1. administration of ionising radiation to participants? |  |  | |
| 1. research overseas? |  |  | |

# 3.2 POTENTIAL RISK TO PARTICIPANTS AND RISK MANAGEMENT PROCEDURES

*Identify, as far as possible, all potential risks to participants (e.g. physical, psychological, social, legal or economic), associated with the proposed research. Please explain what risk management procedures will be put in place.*

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, whether in the 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: <http://the-sra.org.uk/wp-content/uploads/safety_code_of_practice.pdf>

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

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 professional association.*

# 4. INFORMED CONSENT

* 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)*
  2. *Whenever possible, University letterhead should be used for information sheets.)*

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

THE FOLLOWING IS A LIST OF ITEMS NORMALLY EXPECTED TO BE INCLUDED IN AN INFORMATION SHEET. PLEASE USE IT IN CHECKING THAT YOUR DOCUMENTS INCLUDE:

|  |  |  |
| --- | --- | --- |
|  | **YES** | **NOT APPLICABLE** |
| 1. clear identification of the University, the School/Centre (s) involved, the project title, the Principal and other investigators (including contact details) |  |  |
| 1. details of what involvement in the project will require (e.g., involvement in interviews, completion of questionnaire, audio/ video-taping of events), estimated time commitment, any risks involved |  |  |
| 1. advice that the project has received clearance by the University Research Ethics Committee |  |  |
| 1. if the sample size is small, advice to participants that this may have implications for privacy/anonymity |  |  |
| 1. a clear statement that if participants are in a dependent relationship with any of the researchers that involvement in the project will not affect ongoing assessment/grades/management or treatment of health *(as relevant)* |  |  |
| 1. assurance that involvement in the project is voluntary and that participants are free to withdraw consent at any time, and to withdraw any unprocessed data previously supplied |  |  |
| 1. advice as to arrangements to be made to protect confidentiality of data, including that confidentiality of information provided is subject to legal limitations |  |  |
| a statement that the data generated in the course of the research be retained in accordance with the University’s policy on Data Protection and must be kept securely in paper or electronic form for a period of five years after the completion of a research project. |  |  |
| 1. advice that if participants have any concerns about the conduct of this research project that they can contact the Chair of the University Research Ethics Committee at the University |  |  |
| 1. any other relevant information |  |  |

4.2 HAVE YOU ATTACHED TO YOUR APPLICATION A COPY OF THE 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. Whenever possible, University of Bolton letterhead should be used for consent forms.)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | YES |  | NO | *(If NO, please explain how you consent will be documented.)* | |
|  |  | | | |

DOES THE CONSENT FORM INCLUDE THE FOLLOWING:

|  |  |  |  |
| --- | --- | --- | --- |
|  | **YES** | **NO** | **NOT**  **APPLICABLE** |
| 1. appropriate letterhead |  |  |  |
| 1. title of the project and names of investigators |  |  |  |
| 1. confirmation that the project is research |  |  |  |
| 1. confirmation that involvement in the project is voluntary and that participants are free to withdraw at any time, or to withdraw any unprocessed data previously supplied |  |  |  |
| 1. confirmation of particular requirements of participants, including for example whether interviews are to be audio-/video-taped, whether anonymised quotes will be used in publications |  |  |  |
| 1. advice of legal limitations to data confidentiality (in studies where the participants are named or de-identified) |  |  |  |
| 1. if the sample size is small, confirmation that this may have implications for anonymity |  |  |  |
| 1. any other relevant information |  |  |  |

# 5. CONFIDENTIALITY/ANONYMITY

5.1 WILL THE RESEARCH 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)? |  |  |
| 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)? |  |  |
| 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)? |  |  |
| 1. participants having the option of being identified in any publication arising from the research? |  |  |
| 1. participants being referred to by pseudonym in any publication arising from the research? |  |  |
| 1. the use of personal data? *(If YES, you may need to register with the University)* |  |  |
|  |  |  |

*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.*

# 5.2 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 filing cabinets |  |
| 1. access to computer files to be available by password only |  |
| 1. other *(please describe)* |  |

5.3 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.*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | YES |  | NO *(please explain)* | Not applicable | |
|  |  | | | | |

# 6 DATA ACCESS, STORAGE AND SECURITY

6.1 WILL THE PRINCIPAL INVESTIGATOR BE RESPONSIBLE FOR SECURITY OF DATA COLLECTED?

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | YES |  | | NO | *(If NO, please provide further details including any differences between arrangements in the field, and on return to campus.)* | |
|  | | |  | | |

* 1. ACCESS TO DATA

Access by named researchers only

Access by people other than named researcher(s) *(Please explain:)*

* 1. STORAGE OF DATA

Stored at the University of Bolton

Stored at another site *(Please explain where and for what purpose:)*

6.4 DOES DATA STORAGE COMPLY WITH THE UNIVERSITY’S GUIDELINES FOR THE MANAGEMENT OF RESEARCH DATA AND RECORDS?

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

# 7. FUNDING

7.1 IS THIS PROJECT BEING FUNDED?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | YES |  | NO | *(If NO, please skip the remaining questions.)* |

7.2 SOURCE OF FUNDING?

7.3 PROJECT GRANT TITLE AND PROPOSED DURATION OF GRANT *(Where applicable)*

7.4 DOES THE PROJECT REQUIRE APPROVAL BEFORE CONSIDERATION BY A FUNDING AGENCY?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | YES |  | NO |  |

IF YES: DEADLINE FOR THE FUNDING AGENCY?

* 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.*

# 8. CHECKLIST

Please check that the following documents are attached to your application. Please note that where questionnaire or interview questions are submitted in draft form, a copy of the final documentation must be submitted for final approval when available.

|  |  |  |  |
| --- | --- | --- | --- |
|  | ATTACHED | | NOT APPLICABLE |
| Recruitment advertisement (question 2.3) |  |  |  |
| Participant information sheet (question 4.1) |  |  |  |
| Consent form (question 4.2) |  |  |  |
| Evidence of external approvals related to the research (question 1.9) |  |  |  |
| Questionnaire (question 3.1) | draft | final |  |
| Interview Schedule (question 3.1) | draft | final |  |
| Other (please specify:      ) |  |  |  |

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