**Faculty of Medicine, Health and Life Sciences**

**Ethics Application**

**Screening Questionnaire**

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | **Yes** | **No** |
|  | Do you have ethical approval for the study from another recognised Ethics Committee?  *If* ***yes,*** *you should complete the form, Confirmation of Existing Ethical Approval.* |  |  |
|  | Are the proposed participants under the jurisdiction of the prison service?  *If* ***yes****, you will need to apply to the relevant prison ethics committee to obtain ethical approval. You will also need to apply for Faculty REC Approval by completing the Full Ethical Approval Form.* |  |  |
|  | Are the proposed participants to be service users / patients (or family members of service users / patients) recruited from NHS organisations, including hospitals, social care homes, residential care homes, nursing homes?  *If* ***yes****, you will need to apply to the relevant NHS Research Ethics Committee to obtain ethical approval*.  *Please note research with NHS/Trust Staff requires NHS/Trust R&D Governance approval as well as QUB REC Approval* |  |  |
|  | Does this study involve animals?  *If* ***yes*** *and the procedures are covered by the Animal (Scientific Procedures) Act 1986, an application should be submitted to AWERB*  *If* ***yes*** *and the procedures are not covered by the Animal (Scientific Procedures) Act 1986, please complete the form, Animal Welfare Ethical Approval Form. This should be requested by emailing the Research Ethics Officer, at* [*facultyrecmhls@qub.ac.uk*](mailto:facultyrecmhls@qub.ac.uk) |  |  |

**Prior to completion of this application please ensure that you have**

*i. Finalised the protocol*

*ii. Undertaken peer review in accordance with School and University procedures*

*iii. Completed any relevant Health and Safety, and/or Risk Assessment procedures*

**Consideration for Proportionate Review**

Please check the correct box for each question and read the criteria at the end of the screening tool to determine if your application may be considered by the Proportionate Review system or the Full Ethical Approval system.

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | **Yes** | **No** |
|  | Is it your intention to conduct research involving children under 16 with no physical, mental or learning impairment?  *You may submit an application under the Proportionate Review system if this is ‘Yes’. You must indicate in the “Dealing with ethical issues box” how consent will be obtained from the participant’s parents / guardians or responsible adult and how assent will be obtained from the participants.* |  |  |
|  | Is it your intention to conduct research involving potentially vulnerable groups, individuals with mental or learning or behavioural disabilities, victims of crime or events which are stress inducing (e.g. terrorist attacks)? |  |  |
|  | Does your research involve access to records of a personal nature or confidential information (including genetic, health or other biological information) for which specific consent has not been granted for its use for the purposes of the research and it is not anonymised? |  |  |
|  | Does your research involve access to potentially sensitive data through third parties (such as employee data)? |  |  |
|  | Does your research involve a questionnaire which seeks responses about highly sensitive topics for example, sexual behaviour, illegal behaviour, political opinion, religious or spiritual beliefs, race or ethnicity, experience of violence, abuse or exploitation, mental health where the individual’s response can be identified and attributed to the individual? |  |  |
|  | Does your research involve a 1:1 interview with participants which seeks responses about highly sensitive topics for example, sexual behaviour, illegal behaviour, political opinion, religious or spiritual beliefs, race or ethnicity, experience of violence, abuse or exploitation, mental health? |  |  |
|  | Does your research involve a group ‘discussion’ forum which seeks responses about highly sensitive topics for example, sexual behaviour, illegal behaviour, political opinion, religious or spiritual beliefs, race or ethnicity, experience of violence, abuse or exploitation, mental health? |  |  |
|  | Does your research involve respondents participating through social media about highly sensitive issues where the individual’s response can be identified and attributed to the individual? |  |  |
|  | Does your research involve the collection and/or use of human tissue or biological samples from the individual, e.g. saliva? |  |  |
|  | Does your research involve actions with potentially adverse environmental impact? |  |  |
|  | Does your research involve a significant element of deception? |  |  |
|  | Does your research involve participants being asked to undergo invasive procedures, e.g. the administration of drugs or other substances (e.g. food, supplements), vigorous physical exercise, or techniques such as hypnotherapy that would not usually be encountered in everyday life, and are these solely for research purposes? |  |  |
|  | Does your research involve visual/vocal methods where participants or other individuals may be identifiable in the images used or generated, where consent for the use of the images in research has not been obtained? |  |  |
|  | Does your research involve financial inducements (other than reasonable expenses and compensation for time) being offered to participants? |  |  |
|  | Does your research involve covert observation of individuals in non-public places without their consent? |  |  |
|  | Could participation in the research result in psychological stress, anxiety or humiliation or more than minimal pain, that that would not usually be encountered in everyday life? |  |  |
|  | Could participation in the research result in repetitive or prolonged testing such that it may induce fatigue or adverse physical or psychological states? |  |  |
|  | Could participation in the research result in behavioural change through therapeutic interventions, for example, the administration of substances or enrolment in programmes with the specific aim of altering behaviour? |  |  |
|  | Could participation in the research result in ‘labelling’ either by the researcher (e.g. categorisation) or by the participant (e.g. ‘I am stupid’, ‘I am not normal’)? |  |  |
|  | Could participation in the research result in an adverse impact on employment or social standing (e.g. discussion of an employer, discussion of commercially sensitive information)? |  |  |
|  | Could participation in the research result in incidental findings relevant for an individual participant’s health and well-being, such as an indication of underlying physical or emotional ill-health which would require onward referral to a clinician? |  |  |
|  | Does your research involve any elements in addition to the use of cadavers and/or cadaveric specimens (e.g. access to radiological images, access to other data etc.)? |  |  |

If all the answers are **no** then you may complete the Proportionate Review Ethics Application.

If the answer to question 1 is **yes** you may still complete the Proportionate Review Ethics Application but must provide the information required as specified above in the application.

If answers to the questions are yes, other than 1, you must complete the Full Ethics Application.

Please indicate the type of project:

Staff:  Undergraduate (UG):  Postgraduate Taught (PGT):

Postgraduate Research (PGR):

Chief Investigator (This must be a member of QUB staff. For student projects, the Supervisor should be named as the Chief Investigator.)

|  |  |
| --- | --- |
| Name | Click here to enter text. |
| Staff Number | Click here to enter text. |
| School | Click here to enter text. |
| Centre | Click here to enter text. |
| Email Address | Click here to enter text. |

QUB Co-investigators or Students involved

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Staff/Student number | School | Email Address |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
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Non-QUB co-investigators

|  |  |  |
| --- | --- | --- |
| Name | Institution/Company | Email Address |
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| --- | --- |
| Full Title of Research | Click here to enter text. |
| Abbreviated Running Title | Click here to enter text. |
| Proposed Start Date | Click here to enter a date. |
| End Date | Click here to enter a date. |

**Faculty of Medicine, Health and Life Sciences**

**Full Ethics Application**

|  |  |
| --- | --- |
|  | Outline briefly the aims and rationale of your study. Include the main research questions(s) |
|  | |

|  |  |
| --- | --- |
|  | Outline briefly the methods and analysis you intend to use. |
|  | |

**Potential Ethical Issues**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Does the study require participants to disclose information of a sensitive or personal nature?  *If yes, say why this is necessary and what steps have been taken to minimise any adverse effects* | **Yes** | **No** |
|  | | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Does the research have the potential to cause adverse environmental impact?  *If yes, say why this is necessary and what steps have been taken to minimise any adverse effects* | | | **Yes** | | **No** | |
|  | | | | | | | |
|  | | Does the study involve any significant deception or withholding information?  *If yes, say why this is necessary and what steps have been taken to minimise any adverse effects* | **Yes** | | **No** | |
|  | | | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Does your research involve participants being asked to undergo invasive procedures, e.g. the administration of drugs or other substances (e.g. food, supplements), vigorous physical exercise, or techniques such as hypnotherapy that would not usually be encountered in everyday life, and are these solely for research purposes?  *If yes, say why this is necessary and what steps have been taken to minimise any adverse effects* | **Yes** | **No** |
|  | | | |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Does the study involve any visual/vocal methods where participants or other individuals may be identifiable in the images used or generated, where consent for the use of the images in research has not been obtained?  *If yes, say why this is necessary and what steps have been taken to minimise any adverse effects* | **Yes** | **No** |
|  | | | |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Does the study involve the covert observation of individuals in non-public places without their consent?  *If yes, say why this is necessary and what steps have been taken to minimise any adverse effects* | **Yes** | **No** |
|  | | | |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Does the study involve any psychological risk (e.g. stress, anxiety or humiliation) that would not usually be encountered in everyday life?  *If yes, say why this is necessary and what steps have been taken to minimise any adverse effects* | **Yes** | **No** |
|  | | | |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Does the study involve any physical risk (e.g. more than minimal pain, fatigue) that would not usually be encountered in everyday life?  *If yes, say why this is necessary and what steps have been taken to minimise any adverse effects* | **Yes** | **No** |
|  | | | |

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| --- | --- | --- | --- |
|  | Does the study intentionally aim to result in a change in behaviour in the participant?  *If yes, say why this is necessary and what steps have been taken to minimise any adverse effects* | **Yes** | **No** |
|  | | | |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Does your research involve any elements in addition to the use of cadavers and/or cadaveric specimens (e.g. access to radiological images, access to other data etc.)?  *If yes, please outline the additional elements, and describe why these are necessary and what actions will be taken to mitigate any potential ethical issues* | **Yes** | **No** |
|  | | | |

**Participants\***

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | **Experimental** | **Controls** |
|  | How many participants will be involved in the study |  |  |
|  | How many will be students at QUB |  |  |
|  | How many will be adults outside QUB |  |  |
|  | How many will be individuals aged 15 and under |  |  |
|  | How many will be individuals with specific medical conditions |  |  |

\*If a samples based study please provide detail on the samples to be received

|  |  |
| --- | --- |
|  | How will participants be recruited? |
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| --- | --- |
|  | What, if any, inclusion or exclusion criteria will be used? |
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| --- | --- |
|  | What, if any, is the relationship between the investigators and participants (e.g. fellow students, club members, family friends)? |
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|  | How and what will individuals be told about the research?  *(a copy of the Participant Information Sheet must be attached to this application)* |
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| --- | --- |
|  | How will participants provide consent?  *(a copy of the Consent Form (if applicable) must be attached to this application)* |
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|  | If individuals are unable to give consent, e.g. through age or incapacity, how will consent be obtained? |
|  | |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Can the participants withdraw from the research at any time?  *How and when are individuals informed of this?* | **Yes** | **No** |
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| --- | --- |
|  | If individuals wish to withdraw, what will happen to them and their data? |
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| --- | --- | --- | --- |
|  | Are participants being offered any financial inducements (other than reasonable expenses and compensation for time) to participate?  *If yes, explain why this is necessary* | **Yes** | **No** |
|  | | | |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Does the research involve access to records of a personal nature or confidential information (including genetic, health or other biological information) for which specific consent has not been granted for its use for the purposes of the research and it is not anonymised or potentially sensitive data through third parties (such as employee data)?  *If yes, explain how the confidentiality of the information will be preserved* | **Yes** | **No** |
|  | | | |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Could the study result in ‘labelling’ either by the researcher (e.g. categorisation) or by the participant (e.g. ‘I am stupid’, ‘I am not normal’), or an adverse impact on employment or social standing (e.g. discussion of an employer, discussion of commercially sensitive information)?  *If yes, explain how the confidentiality of the information will be preserved* | **Yes** | **No** |
|  | | | |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Could participation in the research result in incidental findings relevant for an individual participant’s health and well-being, such as an indication of underlying physical or emotional ill-health which would require onward referral to a clinician?  *If yes, please state what information the individual will be given, what permission will be obtained, and describe how the information will be handled, e.g. who will it be passed on to.* | **Yes** | **No** |
|  | | | |

**Methods**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Will you be administering any substances to participants? | **Yes** | **No** |
| Will you be asking participants to refrain from taking any substance they would usually take? |  |  |
| *If you have answered yes to either of the above provide the following information for each substance to be administered or withheld:*  *a) substance, b) amount to be administered or withheld, and for how long; c) desired effect, d) possible side effects, and e) what will be done to minimise risks.* | | | |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Will you be administering any questionnaires to participants? | **Yes** | **No** |
| Will you be undertaking any interviews or semi-structured interviews? |  |  |
| *If you have answered yes to either of the above*  *i) for each questionnaire state a) title, b) reference or for unpublished questionnaires provide a copy with the application, c purpose of questionnaire, and/or ii) provide a schedule for the interview.* | | | |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Is permission required from any other source before commencing the research or for the use of equipment?  *If yes, state what permission is required and provide evidence* | **Yes** | **No** |
|  | | | |

**Data security and participant confidentiality**

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|  | Will data be anonymised such that individual responses cannot be identified?  *If yes, describe how you will do this* | **Yes** | **No** |
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| --- | --- |
|  | If data is not anonymised describe what steps will be taken to preserve the confidentiality of the data. |
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|  |  |
| --- | --- |
|  | Where will all forms of the data be stored? |
|  | |

|  |  |
| --- | --- |
|  | Who will have access to the data? |
|  | |

|  |  |
| --- | --- |
|  | Where will Consent Forms be stored? |
|  | |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Will individually identifiable information be given to third parties or available through publications, etc?  *If yes, state why this is necessary and demonstrate that participants are made aware of this.* | **Yes** | **No** |
|  | | | |

**To be confirmed by Chief Investigator / Supervisor:**

|  |  |
| --- | --- |
| I confirm that the protocol has been peer reviewed in accordance with School and University procedures and is deemed to be viable and scientifically valid. The submitted study documents have been revised following peer review comments, as appropriate.  *A copy of the Peer Review(s) should be submitted with the application* |  |
| I confirm that the relevant risk assessment and health and safety protocols in relation to this research have been undertaken and appropriate safeguards in place to manage any risks. |  |
| I believe that the research does not raise significant ethical issues. |  |
|  |  |
| **By submitting this application all applicants confirm :** |  |
| I will preserve the confidentiality of all information provided by participants in this research. |  |
| I will abide by the procedures established by the University, relevant professional bodies and other organisations in conducting this research. |  |
| I will conduct the research in accordance with the protocol supplied. |  |
| I have consulted the appropriate Codes of Practice for my professional body. |  |

Signature of Chief Investigator/Supervisor:

(Electronic signature acceptable)

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QUB Staff Number of Chief Investigator/Supervisor:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Submission:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

This application form and the material indicated below should be submitted by email from the Chief Investigator/Supervisor to:

[facultyrecmhls@qub.ac.uk](mailto:facultyrecmhls@qub.ac.uk)

* Please ensure that all study documents are marked with a version number and date in the header or footer.
* All documents listed below that are applicable to the application must be submitted so that the application pack clearly describes the study and is complete with all required documentation.
* If your submission has multiple documents of the same type e.g. consent form, please use separate rows.
* If a document listed below is not applicable to your study please enter "N/A" in the ‘enclosed’ column:

|  |  |  |  |
| --- | --- | --- | --- |
| Study Document | Enclosed | Version | Date |
| Full Ethics Application Form | Mandatory |  |  |
| Research Protocol | Mandatory |  |  |
| Recruitment material, e.g. Invitation Letter/e-mail, Posters/Flyers and Social Media Posts | Yes/No |  |  |
| Participant Information Sheet(s) e.g. Participant, Child, Parent Information Sheet | Yes/No |  |  |
| Participant Consent Form(s) including Assent Form if children under 16 are recruited | Yes/No |  |  |
| Any published/unpublished questionnaires/surveys (including all measures/scales/demographics etc.) | Yes/No |  |  |
| Interview Schedule(s) | Yes/No |  |  |
| Focus Group Schedule(s) | Yes/No |  |  |
| Workshop Schedule(s)/Agenda | Yes/No |  |  |
| Any relevant permissions, e.g. to access participants, letter of support etc. | Yes/No |  |  |
| Copy of Peer Reviews – 2 x Gov4 Peer Reviews (all submitted documents should be revised to reflect any peer review comments, as appropriate) | Mandatory |  |  |
| Any other documents/information (please list below, one row per additional document): | Yes/No |  |  |
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If you require any information in respect of the above application, please contact the University Research Ethics Officer, [facultyrecmhls@qub.ac.uk](mailto:facultyrecmhls@qub.ac.uk), tel 2529.