**Ethics Application Form**

OFFICE USE ONLY
UECREF
Date
Paper

Please answer all questions

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| **1. Title of the investigation** |
|       |
| Please state the title on the PIS and Consent Form, if different:      |

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| **2. Chief Investigator (must be at least a Grade 7 member of staff or equivalent)** |
| Name:      [ ]  Professor[ ]  Reader[ ]  Senior Lecturer[ ]  Lecturer[ ]  Senior Teaching Fellow[ ]  Teaching FellowDepartment:      Telephone:       E-mail:       |

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| **3. Other Strathclyde investigator(s)** |
| Name:      Status (e.g. lecturer, post-/undergraduate):      Department:      Telephone:       E-mail:       |

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| **4. Non-Strathclyde collaborating investigator(s) (where applicable)** |
| Name:      Status (e.g. lecturer, post-/undergraduate):      Department/Institution:      If student(s), name of supervisor:      Telephone:       E-mail:      Please provide details for all investigators involved in the study:       |

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| **5. Overseas Supervisor(s) (where applicable)** |
| Name(s):      Status:      Department/Institution:      Telephone:       Email:       I can confirm that the local supervisor has obtained a copy of the Code of Practice: Yes [ ]  No [ ] Please provide details for all supervisors involved in the study:       |

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| **6. Location of the investigation** |
| At what place(s) will the investigation be conducted       |
| If this is not on University of Strathclyde premises, how have you satisfied yourself that adequate Health and Safety arrangements are in place to prevent injury or harm?       |

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| **7. Duration of the investigation**  |
| Duration(years/months) :     Start date (expected):      /      /      Completion date (expected):      /      /      |

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| **8. Sponsor** Please note that this is not the funder; refer to Section C and Annexes 1 and 3 of the Code of Practice for a definition and the key responsibilities of the sponsor. |
| Will the sponsor be the University of Strathclyde: Yes [ ]  No [ ] If not, please specify who is the sponsor:       |

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| **9. Funding body or proposed funding body (if applicable)** |
| Name of funding body:      Status of proposal – if seeking funding (please click appropriate box):[ ]  In preparation[ ]  Submitted[ ]  AcceptedDate of submission of proposal:      /      /      Date of start of funding:      /      /      |

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| **10. Ethical issues** |
| Describe the main ethical issues and how you propose to address them:      |

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| **11. Objectives of investigation (including the academic rationale and justification for the investigation)** Please use plain English. |
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| **12. Participants** |
| Please detail the nature of the participants:      Summarise the number and age (range) of each group of participants:Number:       Age (range)      Please detail any inclusion/exclusion criteria and any further screening procedures to be used:      |

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| **13. Nature of the participants** Please note that investigations governed by the Code of Practice that involve any of the types of participants listed in B1(b) must be submitted to the University Ethics Committee (UEC) rather than DEC/SEC for approval. |
| Do any of the participants fall into a category listed in Section B1(b) (participant considerations) applicable in this investigation?: Yes [ ]  No [ ] If yes, please detail which category (and submit this application to the UEC):        |

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| **14. Method of recruitment** |
| Describe the method of recruitment (see section B4 of the Code of Practice), providing information on any payments, expenses or other incentives.      |

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| **15. Participant consent** |
| Please state the groups from whom consent/assent will be sought (please refer to the Guidance Document). The PIS and Consent Form(s) to be used should be attached to this application form.      |

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| **16. Methodology**Investigations governed by the Code of Practice which involve any of the types of projects listed in B1(a) must be submitted to the University Ethics Committee rather than DEC/SEC for approval.  |
| Are any of the categories mentioned in the Code of Practice Section B1(a) (project considerations) applicable in this investigation? [ ]  Yes [ ]  No If ‘yes’ please detail:       |
| Describe the research methodology and procedure, providing a timeline of activities where possible. Please use plain English.      |
| What specific techniques will be employed and what exactly is asked of the participants? Please identify any non-validated scale or measure and include any scale and measures charts as an Appendix to this application. Please include questionnaires, interview schedules or any other non-standardised method of data collection as appendices to this application.       |
| Where an independent reviewer is not used, then the UEC, DEC or SEC reserves the right to scrutinise the methodology. Has this methodology been subject to independent scrutiny? Yes [ ]  No [ ]  If yes, please provide the name and contact details of the independent reviewer:       |

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| **17. Previous experience of the investigator(s) with the procedures involved.** Experience should demonstrate an ability to carry out the proposed research in accordance with the written methodology. |
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| **18. Data collection, storage and security** |
| How and where are data handled? Please specify whether it will be fully anonymous (i.e. the identity unknown even to the researchers) or pseudo-anonymised (i.e. the raw data is anonymised and given a code name, with the key for code names being stored in a separate location from the raw data) - if neither please justify.      |
| Explain how and where it will be stored, who has access to it, how long it will be stored and whether it will be securely destroyed after use. In line with the University’s commitment to [Open Research](https://www.strath.ac.uk/research/openresearch/), it is expected that fully anonymised, completed research data will not be destroyed, but will be deposited into Pure or other repository. Please ensure that research data is managed in accordance with the University’s [Research Data Management and Sharing Policy](https://www.strath.ac.uk/media/ps/cs/gmap/academicaffairs/policies/Research_Data_Management_and_Sharing_Policy.pdf)      |
| Will anyone other than the named investigators have access to the data? Yes [ ]  No [ ] If ‘yes’ please explain:      |

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| **19. Potential risks or hazards** |
| Briefly describe the potential Occupational Health and Safety (OHS) hazards and risks associated with the investigation:       |
| Please attach a completed eRisk Assessment for the research. Further Guidance on Risk Assessment and Form can be obtained on [Occupational Health, Safety and Wellbeing’s webpages](https://www.strath.ac.uk/safetyservices/documentationforms/forms/) |

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| **20. What method will you use to communicate the outcomes and any additional relevant details of the study to the participants?** |
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| **21. How will the outcomes of the study be disseminated (e.g. will you seek to publish the results and, if relevant, how will you protect the identities of your participants in said dissemination)?**  |
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| **Checklist** | **Enclosed** | **N/A** |
| Participant Information Sheet(s)Consent Form(s)Sample questionnaire(s)Sample interview format(s)Sample advertisement(s)OHS Risk Assessment (S20)Any other documents (please specify below)                          | [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]  | [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]  |

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| **22. Chief Investigator and Head of Department Declaration**Please note that unsigned applications will not be accepted and both signatures are required |
| I have read the University’s Code of Practice on Investigations involving Human Beings and have completed this application accordingly. By signing below, I acknowledge that I am aware of and accept my responsibilities as Chief Investigator under Clauses 3.11 – 3.13 of the [Research Governance Framework](http://www.cso.scot.nhs.uk/wp-content/uploads/2013/02/RGF-Second-Edition-February-06.pdf) and that this investigation cannot proceed before all approvals required have been obtained. |
| Signature of Chief Investigator  |  |  |
| Please also type name here:  |       |
| I confirm I have read this application, I am happy that the study is consistent with departmental strategy, that the staff and/or students involved have the appropriate expertise to undertake the study and that adequate arrangements are in place to supervise any students that might be acting as investigators, that the study has access to the resources needed to conduct the proposed research successfully, and that there are no other departmental-specific issues relating to the study of which I am aware. |
| Signature of Head of Department  |  |  |
| Please also type name here |       |
| Date: |      /      /      |

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| **23. Only for University sponsored projects under the remit of the DEC/SEC, with no external funding and no NHS involvement** |
| **Head of Department statement on Sponsorship** This application requires the University to sponsor the investigation. This is done by the Head of Department for all DEC applications with exception of those that are externally funded and those which are connected to the NHS (those exceptions should be submitted to R&KES). I am aware of the implications of University sponsorship of the investigation and have assessed this investigation with respect to sponsorship and management risk. As this particular investigation is within the remit of the DEC and has no external funding and no NHS involvement, I agree on behalf of the University that the University is the appropriate sponsor of the investigation and there are no management risks posed by the investigation.If not applicable, tick here [ ]  |
| Signature of Head of Department  |  |  |
| Please also type name here |       |
| Date: |      /      /      |
| For applications to the University Ethics Committee, the completed form should be sent to ethics@strath.ac.uk with the relevant electronic signatures. |

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| **24. Insurance**  |
| The questionnaire below must be completed and included in your submission to the UEC/DEC/SEC: |

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| Is the proposed research an investigation or series of investigations conducted on any person for a Medicinal Purpose?Medicinal Purpose means: * treating or preventing disease or diagnosing disease or
* ascertaining the existence degree of or extent of a physiological condition or
* assisting with or altering in any way the process of conception or
* investigating or participating in methods of contraception or
* inducing anaesthesia or
* otherwise preventing or interfering with the normal operation of a physiological function or
* altering the administration of prescribed medication.
 | Yes / No |

If “**Yes**” please go to **Section A (Clinical Trials)** – all questions must be completed

If “**No**” please go to **Section B (Public Liability)** – all questions must be completed

**Section A (Clinical Trials)**

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| Does the proposed research involve subjects who are either:1. under the age of 5 years at the time of the trial;
2. known to be pregnant at the time of the trial
 | Yes / No |

*If “****Yes****” the UEC should refer to Finance*

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| Is the proposed research limited to:1. Questionnaires, interviews, psychological activity including CBT;
2. Venepuncture (withdrawal of blood);
3. Muscle biopsy;
4. Measurements or monitoring of physiological processes including scanning;
5. Collections of body secretions by non-invasive methods;
6. Intake of foods or nutrients or variation of diet (excluding administration of drugs).
 | Yes / No |

*If ”****No****” the UEC should refer to Finance*

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| Will the proposed research take place within the UK? | Yes / No |

 *If “****No****” the UEC should refer to Finance*

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|  Title of Research |  |
| Chief Investigator |  |
| Sponsoring Organisation |  |
| Does the proposed research involve: |
| 1. investigating or participating in methods of contraception?
 | Yes / No |
| 1. assisting with or altering the process of conception?
 | Yes / No |
| 1. the use of drugs?
 | Yes / No |
| 1. the use of surgery (other than biopsy)?
 | Yes / No |
| 1. genetic engineering?
 | Yes / No |
| 1. participants under 5 years of age(other than activities i-vi above)?
 | Yes / No |
| 1. participants known to be pregnant (other than activities i-vi above)?
 | Yes / No |
| 1. pharmaceutical product/appliance designed or manufactured by the institution?
 | Yes / No |
| 1. work outside the United Kingdom?

Note that this refers to the location of the researchers only, not to the location of participants:Answer ‘yes’ if any University staff or students will be located overseas while conducting the research.Answer ‘no’ if all University staff or students will be located in the UK, for example, conducting online research with participants who are located overseas. | Yes / No |

If **“YES”** to **any** of the questions a-i please also complete the **Employee Activity Form** (attached).

If **“YES”** to **any** of the questions a-i, and this is a follow-on phase, please provide details of SUSARs on a separate sheet.

*If “****Yes****” to any of the questions a-i then the UEC/DEC/SEC should refer to Finance (*insurance-services@strath.ac.uk*).*

**Section B (Public Liability)**

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| Does the proposed research involve : |
| 1. aircraft or any aerial device
 | Yes / No |
| 1. hovercraft or any water borne craft
 | Yes / No |
| 1. ionising radiation
 | Yes / No |
| 1. asbestos
 | Yes / No |
| 1. participants under 5 years of age
 | Yes / No |
| 1. participants known to be pregnant
 | Yes / No |
| 1. pharmaceutical product/appliance designed or manufactured by the institution?
 | Yes / No |
| 1. work outside the United Kingdom?

Note that this refers to the location of the researchers only, not to the location of participants:Answer ‘yes’ if any University staff or students will be located overseas while conducting the research.Answer ‘no’ if all University staff or students will be located in the UK, for example, conducting online research with participants who are located overseas. | Yes / No |

*If* ***“YES”*** *to any of the questions the UEC/DEC/SEC should refer to Finance (*insurance-services@strath.ac.uk*).*

**For NHS applications only - Employee Activity Form**

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| Has NHS Indemnity been provided? | Yes / No |
| Are Medical Practitioners involved in the project? | Yes / No |
| If YES, will Medical Practitioners be covered by the MDU or other body? | Yes / No |

This section aims to identify the staff involved, their employment contract and the extent of their involvement in the research (in some cases it may be more appropriate to refer to a group of persons rather than individuals).

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| **Chief Investigator** |
| **Name** | **Employer** | **NHS Honorary Contract?** |
|  |  | Yes / No |
| **Others** |
| **Name** | **Employer** | **NHS Honorary Contract?** |
|  |  | Yes / No |
|  |  | Yes / No |
|  |  | Yes / No |
|  |  | Yes / No |

Please provide any further relevant information here: