School of Health and Social care



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| **Ethics Checklist**  |

The ethics checklist determines whether the research is high-risk or not.

If you answer **NO** to **ALL** of the questions please ***send the completed checklist to SHSC ethics.***

If you answer **YES** to **ANY** of the questions please complete the ***SHSC Ethics Approval Forms or External Application [see questions 1-4] if appropriate, along with any supporting documentation.***

 **Ethics Checklist**

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| **If your answer to any of the following questions (1 – 4) is YES, you must apply to an appropriate external ethics committee for approval:** | *Delete as appropriate* |
| 1. | Does your research involve recruiting current NHS patients or staff or accessing NHS data? If you are unsure, please check at <http://www.hra.nhs.uk/research-community/before-you-apply/determine-which-review-body-approvals-are-required/>)(Such research will require approved by an external ethics committee such as NHS Research Ethics Committee)  | **Yes/No** |
| 2. | Will you recruit any participants who are unable to consent for themselves, i.e. Adults with Incapacity? If you are unsure please check at <https://www.legislation.gov.uk/asp/2000/4/contents>(Such research needs to be approved by an external ethics committee such as AWI Research Ethics Committee - Scotland A REC) | **Yes/No** |
| 3. | Will you recruit any participants who are currently under the auspices of the Criminal Justice System, for example, but not limited to, people on remand, prisoners and those on probation? (Such research needs to be authorised by the ethics approval system of the NRES Central Allocation System, CAS) | **Yes/No** |
| 4. | Does your research involve recruiting participants from overseas or involves the researcher collecting data in other countries | **Yes/No** |

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| **Research Safety** | *Delete as appropriate* |
|  5.1. | Does the proposed research pose any particular risks to the researcher(s) and/or research participants (see Risk Assessment Form and Adverse Events Standard Operating Procedures – add Links) | **Yes/No** |
| 5.2. | Will the research involve lone working, which is defined as someone working away from any immediate colleague, off-campus/site and is applicable to those carrying out interviews on their own (see Lone Working Policy – add Links) | **Yes/No** |

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| **Research Involving Human Participants** | *Delete as appropriate* |
| 6. | Does your research involve participants who are unable to give informed consent, for example, but not limited to, people who may have a degree of learning disability or mental health problem, that means they are unable to make an informed decision on their own behalf?  | **Yes/No** |
| 7.  | Does your research involve participants under the age of 18 years? | **Yes/No** |
| 8. | Is there a risk that your research might lead to disclosures from participants concerning their involvement in illegal activities? | **Yes/No** |
| 9. | Is there a risk that obscene and or illegal material may need to be accessed for your research study (including online content and other material)? | **Yes/No** |
| 10. | Does your research involve participants disclosing information about sensitive or controversial topics? | **Yes/No** |
| 11.  | Does your research involve the researcher travelling to another country or involve participants outside the UK? | **Yes/No** |
| 12.  | Does your research involve invasive or intrusive procedures? For example, these may include, but are not limited to, electrical stimulation, heat, cold or bruising, blood sampling. | **Yes/No** |
| 13. | Does your research involve the administration of drugs, placebos or other substances to study participants? | **Yes/No** |
| 14.  | Does the proposed research involve intrusive and/or physical interventions e.g, use of physical exercise; exposure to additional physiological tests (invasive and non-invasive); collection of tissue? | **Yes/No** |
| 15. | Does the research involve a non Conformité Européene(CE) marked medical device or a device which has been modified outside of its CE mark? | **Yes/No** |
| 16.  | Does your research involve adults who are vulnerable because of their social, psychological or medical circumstances (vulnerable adults)? This includes adults with cognitive and / or learning disabilities, adults with physical disabilities and older people. | **Yes/No** |
| 17. | Does the research involve participants who have particular communication/linguistic or developmental requirements? | **Yes/No** |
| 18. | Does the proposed research involve the processing of information held by external agencies/third parties without consent? | **Yes/No** |
| 19. | Does the research involve the bodies of human materials from deceased persons? | **Yes/No** |
| 20. | Does your research involve intentional deception, concealment or covert observation? | **Yes/No** |
| 21. | Does the research involve interviews with participants or use of questionnaires? | **Yes/No** |
| 22. | Does the proposed research involve sensitive or controversial topics? | **Yes/No** |
| 23. | Could the proposed research induce psychological stress, anxiety, and humiliation or cause more than minimal pain? | **Yes/No** |

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| **Research impacting on animals and other considerations** |  *Delete as appropriate* |
| 24. | Does the proposed research involve animals or disturbance to any animal? | **Yes/No** |

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| **Data management and resource considerations** | *Delete as appropriate* |
| 26. | Does the proposed research involve accessing records of personal or confidential information? | **Yes/No** |
| 27. | Does the proposed research involve recording participants or use of audio-visual material for which consent is required? | **Yes/No** |
| 28. | Does the research involve remote acquisition of data or accessing sensitive information through third parties, internet or associated technologies? | **Yes/No** |
| 29. | Does the research involve reproducing copyrighted work, e.g. using a validated questionnaire? | **Yes/No** |
| 30.  | Does the proposed work involve a potential conflict of interest or raise ethical issues regarding sources of funding or where publication of research data may be restricted? | **Yes/No** |
| 31.  | Will the identity of the participant be linked directly or indirectly to the data? | **Yes/No** |
| 32.  | Will payment or reward be made to participants, beyond reimbursement of out of pocket expenses/refreshments? | **Yes/No** |
| 33. | If the project is unfunded, does the project require resources (including staff time) to undertake this project that have not been agreed or supported by line manager/supervisor. | **Yes/No** |
| 34. | If project funded, does the work involve conflict of interest or raise ethical issues regarding funding source? | **Yes/No** |

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| **Insurance and Indemnity considerations** |  *Delete as appropriate* |
| 35. | Is your research covered by normal university insurance coverage <http://staff.napier.ac.uk/services/finance/Pages/InsuranceCertificates.aspx> (if unsure complete questions 35.1-7 and if any questions are no, please contact insurance@napier.ac.uk for advice) | **Yes/No/****Unsure** |
| 35.1. | Is your research a clinical trial involving participants under 5 years? Trials involving subjects under 5 years of age? | **Yes/No** |
| 35.2. | Is your research a clinical trial assisting with or altering in any way the process of conception? | **Yes/No** |
| 35.3. | Is your research a clinical trial investigating or participation in methods of contraception? | **Yes/No** |
| 35.4.  | Is your research a clinical trial involving genetic engineering other than for preventing and diagnosing disease | **Yes/No** |
| 35.5.  | Is your research a clinical trial involving drugs or surgery or nutrients? | **Yes/No** |
| 35.6.  | Is your research a clinical trial involving persons known to be pregnant? | **Yes/No** |
| 35.7. | Is your research a clinical trial involving products manufactured by the University? | **Yes/No** |

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| **Additional considerations** |  |
| 36. | Does the research raise any ethical issues not covered by questions 1-35? If yes please provide further information: | **Yes/No** |

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| **You can submit the completed checklist if your answer to all questions is “NO” complete the** **applicant details below and submit the completed checklist to SHSC ethics.****Please note the full SHSC Research Ethics Approval Form must be completed and forwarded to SHSC ethics if you have answered YES to any of the above questions for full consideration by the SHSC RIC ethical approvals committee (see SHSC Ethical Review Flow Chart – add Link). If unsure please submit your checklist for review.** |

Applicant Details

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| **1** | **Name of Applicant:** | **Address:** |
|  |  |  **Email:** **Phone:** |
| **2** | **Staff only (job title):****Co-applicants:** |
| **3** | **Students only****Degree Programme: Module code (if applicable):****DOS and/or supervisors:**  |
| **4** | **Project Title:**      |
| **5** | **Project start date:**       | **Project end date:**       |
| **7** | **Where will research take place**      |
| **8** | **Short project description (500 words):**      |
| **9** | **Other Information** (provide any other information which you believe should be taken into account during ethical review)      |

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| By signing below (digital signatures accepted), you certify that the information provided is accurate and true reflection of the study. Applicants should expect to get an acknowledgment within 3-5 working days that their checklist has been received. If you do not hear, please contact ethics, shsc@napier.ac.uk**Applicant’s Signature:** |  |
| **Date:****Supervisor’s signature (students only):****Date:** |  |

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| FOR OFFICE USE ONLY:Date received ………………… Reference number……………….. |
| Application/checklist completed with appropriate supporting documents, signed and dated [ ]  For archiving [ ] Further ethical review required Yes[ ]  No [ ] Signature of the RIC Committee Member: …………………………. Date: ………………………  |