SHSC Ethical Approval

1. **Research Details**

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| **Name of Lead Researcher (PI):** |  |
| **Names of other Researchers/DOS/Supervisors** |  |
| **School or Professional service department:** |  |
| **Email:** |  |
| **Contact number:** |  |
| **Project Title:** |  |
| **Start Date:** |  |
| **End Date:** |  |
| **Is anybody funding this research? (Amount and Source)** |  |
| **Type of Research: UG/Taught PG/Masters/Doctoral Student/ Staff/External** | |
| **Name of Independent Advisor** |  |

1. **Screening Questions**

Please answer the following questions to identify the level of risk in the proposed project:

**If you answer ‘No’ to all questions, please complete Section 3a only.**

**If you have answered ‘Yes’ to any of the questions 7-17 please complete Section 3a and 3b.**

**If you have answered ‘Yes to any of the questions 1-6, complete all of Section 3.**

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|  | **You Must Answer All Questions** | **Yes** | **No** |
| 1. | Is the research a Clinical Trial? |  |  |
| 2. | Is the research in a health care setting? |  |  |
| 3. | Is the research investigating socially or culturally ‘controversial’ topics (for example pornography, extremist politics, or illegal activities)? |  |  |
| 4. | Will any covert research method be used? |  |  |
| 5. | Will the research involve deliberately misleading participants (deception) in any way? |  |  |
| 6. | Does the research involve the researcher travelling to another country or involve participants outside the UK? |  |  |
| 7. | Does the Research involve staff or students within the University? |  |  |
| 8. | Does the Research involve vulnerable people? (For example people under 18 or over 70 years of age, disabled (either physically or mentally), those with learning difficulties, people in custody, migrants etc). |  |  |
| 9. | Is the information gathered from participants of a sensitive or personal nature? |  |  |
| 10. | Is there any realistic risk of any participants experiencing either physical or psychological distress or discomfort? |  |  |
| 11. | Have you identified any potential risks to the researcher in carrying out the research? (for example physical/emotional/social/economic risks?) |  |  |
| 12. | Is there a possible conflict of interest between researcher and participant that would affect the voluntary nature of the participation, e.g. managerial influence, Research using current students as participants? |  |  |
| 13. | Will the research require the use of assumed consent rather than informed consent? (For example when it may be impossible to obtain informed consent due to the setting for the research – e.g. observational studies/videoing/photography within a public space) |  |  |
| 14. | Is there any risk to respondents’ anonymity in any report/thesis/publication from the research, even if real names are not used? |  |  |
| 15. | Will any payment or reward be made to participants, beyond reimbursement or out-of-pocket expenses? |  |  |
| 16. | Does the research require external ethics clearance? (For example from the NHS or another institution) |  |  |
| 17. | Does the research involve the use of secondary datasets? |  |  |

**3A. Details of Project**

In this section please provide details of your project and outline data collection methods, how participant consent will be given as well as details of storage and dissemination.

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| **Please give a 300 word overview of the research project** | |
| **Background information** *(300 words maximum; references should be cited and listed)*  Click here to enter text.  **Justification for the research (what might the impact on your practice or the practice of others)?**  Click here to enter text.  **Aims and/or research questions**  Click here to enter text.  **References**  Click here to enter text. | |
| **Data Collection** | |
| **1.** | **Who will be the participants in the research?** |
|  | ***Number & nature of sample (include sample size calculation if applicable):*** Click here to enter text.  ***Inclusion/exclusion criteria:*** Click here to enter text. |
| **2.** | **How will you collect and analyse the research data? (please outline all methods e.g. questionnaires/focus groups/internet searches/literature searches/interviews/observation)** |
|  | ***Please explain the reason for the particular method, estimated time commitment and how data will be analysed.***  Click here to enter text. |
| **3.** | **Where will the data will be gathered (e.g. in the classroom/on the street/telephone/online)** |
|  | ***Focus group/interviews (provide details of themes/questions)***  ***Audio/video recordings (provide details, ensure permission is evidenced on consent form)***  ***Questionnaire (provide copy of questions or online link)***  ***Participant observation (provide observation proforma)***  ***Other***  Click here to enter text. |
| **4.** | **Risk Assessment. It should be clear from the comments provided that the potential risks have been considered and information provided on what they are, with evidence of what is being implemented to mitigate these (please consult Risk Assessment Guidance).** |
|  | ***Comment on the potential risks to participant***  Click here to enter text.  ***Comment on the potential risk to researcher***  Click here to enter text. |
| **5.** | **Does the project involve field work, lone working or travel to unfamiliar place (e.g. off campus) (please consult Risk Assessment Guidance)** |
|  | Click here to enter text. |
| **6.** | **If your research is based on secondary data, please outline the source, validity and reliability of the data set** |
|  | Click here to enter text. |
| **Consent and Participant Information** | |
| **7.** | **How will you invite research participants to take part in the study? (e.g letter/email/asked in lecture)** |
|  | ***Recruitment of participants:*** Click here to enter text. |
| **8.** | **How will you explain the nature and purpose of the research to participants?** |
|  | Click here to enter text. |
| **9.** | **How will you record obtaining informed consent from your participants?** |
|  | Click here to enter text. |
| **Data storage and Dissemination** | |
| **10.** | **How, where and in what format will data be stored? And what steps will be taken to ensure data is stored securely?** |
|  | **Location of storage**  **Data identifiers kept in a secure room/facility**  **Electronic data password protected**  Click here to enter text. |
| **11.** | **Who will have access to the data?** |
|  | Click here to enter text. |
| **12.** | **What methods are used to protect the privacy of the participants, including the degree anonymity?** |
|  | Click here to enter text. |
| **13.** | **How long will the data be kept?** |
|  | Click here to enter text. |
| **14.** | **What will be done with the data at the end of the project?** |
|  | Click here to enter text. |
| **15.** | **How will the findings be disseminated, including made available to participants?** |
|  | Click here to enter text. |
| **16.** | **Will any individual be identifiable in the findings?** |
|  | Click here to enter text. |

**3B. Identification and Mitigation of Potential risks**

This section is designed to identify any realistic risks to the participants and how you propose to deal with it.

1. **Does this research project involve working with potentially vulnerable individuals?**

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| **Group** | **Yes** | **NO** | **Details (for example programme student enrolled on, or details of children’s age/care situation, disability)** |
| **Students at ENU** |  |  |  |
| **Staff at ENU** |  |  |  |
| **Children under 18** |  |  |  |
| **Pregnant persons** |  |  |  |
| **Elderly (over 70)** |  |  |  |
| **Physical disabilities** |  |  |  |
| **Migrant workers** |  |  |  |
| **Prisoners / people in custody** |  |  |  |
| **Cognitive problems/Learning difficulties** |  |  |  |
| **Linguistic/communication difficulties** |  |  |  |

1. **If you are recruiting children (under 18 years) or people who are otherwise unable to give informed consent, please give full details of how you will obtain consent from parents, guardians, carers etc.**

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1. **Please describe any identified risks to participants or the researcher as a result of this research being carried out.**

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1. **Please describe what steps have been taken to reduce these identified risks? (for example providing contact details for appropriate support services (e.g. University Counselling, Samaritans), reminding participants of their right to withdraw and/or not answering questions, or providing a full debriefing to participants and understanding the responsibility of the researcher when dealing with confidential and sensitive information).**

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1. **If you plan to use assumed consent rather than informed consent please outline why this is necessary.**

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1. **If payment or reward will be made to participants please justify that the amount and type are appropriate (for example the amount should not be so high that participants would be financially coerced into taking part, or that the type of reward is appropriate to the research topic).**

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**3C. Justification of High Risk Projects**

If you answered ‘Yes’ to the screening questions 1-6 this section asks for justification on the choice of research topic and methodology. The Reviewers have the right to refer high risk applications to the Research Integrity Committee for approval.

1. **If you have answered yes to question 1, please give a full description of all clinical procedures (Note this is for non-NHS studies only. If the study involves NHS participants, staff or premises please complete the IRAS application and submit PDF for risk assessment)**

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1. **If you have answered yes to question 2, please give a full description of the health care setting and what steps have been taken to reduce any potential risks and describe how you have gained permission from the Organisation.**

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1. **If you have answered yes to questions 3 (research into a controversial topic), please provide a justification for your choice of research topic, and describe how you would deal with any potential issues arising from researching that topic.**

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1. **If you have answered yes to questions 4 or 5 (use of deception or covert research methods) please provide a justification for your choice of methodology, and state how you will mitigate the risks associated with these approaches**.

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1. **If you have answered yes to questions 6 (overseas research) please provide details on how the research will be conducted in another country (note the research should comply with UK ethical and legal requirements). Please state the procedures/permissions for ethical approval and the sponsorship agreement with the relevant institution(s) in the country where the research will be conducted. Note it will be important to ensure that the research is covered by the University Insurance coverage.**

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| **Declaration**  **The application will NOT be accepted if this section is blank or incomplete** | | |
| * The information contained herein is, to the best of knowledge and belief, accurate * **The project will abide by the Edinburgh Napier University’s policies and procedures** * **I undertake to inform the SHSC ethics of significant changes and amendments to the protocol** * **I am aware of my responsibility to be up to date and comply with the requirements of law and relevant guidelines relating to security and confidentiality of personal data.** * **I understand that the project, including research records and data may be subject to inspection for audit purposes, if required in the future.**   **Pease note that by submitting this application the supervisor confirms that:**   * The student is aware of the School ethics requirements * **The topic merits further research** * **The student has relevant skills to begin research** * **The procedures for collecting data, recruitment and obtaining informed consent are appropriate** * **Required resources/support have been approved for this study by Head of School/Director of Research.**   **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 working days that their application for full ethical review, including all supporting documents have been received. If you do not hear, please contact SHSC ethics -** [ethics.shsc@napier.ac.uk](mailto:ethics.shsc@napier.ac.uk) | | |
|  | I confirm that I have considered the ethical risks arising from this project and have provided accurate information and the research will be conducted in the manner described. | |
| **Researcher Signature:** | | **Date:** |
| **Director of Studies/Supervisor/Principal Investigator Signature:** | | **Date:** |

**Application Form Checklist**

All applications require the following to be submitted with the application form

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| **All relevant fields are completed** |  |
| **Application is submitted 4 weeks in advance of data collection** |  |
| **Includes a Participant Information Sheet (plain language summary) on headed paper** |  |
| **Includes an Informed Consent Form on headed paper** |  |
| **Includes Protocol/Interview/Survey Questions/Recruitment Poster/Debrief (as required)** |  |
| **Has attached written permission(s) from relevant outside organisation(s) (as required)** |  |
| **Includes completed risk assessment** |  |
| **Includes data management assessment** |  |
| **Includes privacy statement (students should also provide an oath of confidentiality)** |  |
| **The declaration is signed and dated** |  |
| **The Director of Studies/Supervisor(s) have read, signed and dated the declaration (student requirement)?** |  |

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| FOR OFFICE USE ONLY:  Date received …………………  Reference number……………….. |
| Appropriate supporting documents, signed and dated |