**School of Health in Social Science Research Ethics Application**

**The supervisor or primary investigator must complete and sign this form after checking that all relevant sections are completed, and relevant documents are attached. For all undergraduate (UG) and MSc student projects, it is the supervisor’s responsibility to submit this form and all attachments. Please note that failure to do this will result in the application being returned (and not processed) causing your research to be delayed.**

|  |  |
| --- | --- |
| **Supervisor (name and UUN:** | |
| **Primary Investigator (name and UUN):** | |
| **List of all collaborators (with affiliated institutions in brackets):** | |
| **Student’s programme of study (if applicable):** | |
| **Project Title:** | |
| **Case Number (if known – assigned by Administrator at time of 1st submission):** | |
| **Proposed Project Start Date:** | **Proposed Project End Date:** |

**Please indicate whether the primary investigator on this project is staff or student and select your subject area:**

Staff  UG or MSc Student  DClin Student  PhD Student

CPASS  Clinical Psychology  Nursing Studies

**This is a:**

New application for ethical review – first submission

Resubmission following reviewer comments

Resubmission with requested amendments

**Has been reviewed by an external ethical board, such as NHS IRAS or a UK HEI (multi-site studies only) with a favourable opinion? Level 1** \*

IRAS (NHS research ethics)  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Please tick one option that best describes your application:**

Collecting or generating new data involving other people: Level 2

Extracting, re-coding and analysing existing data that contains sensitive information (i.e. identifiable information): Level 2

Analysing secondary (archival) data that is routinely collected or is an existing anonymised dataset: Level 1

Collecting new data BUT an external ethical review board (such as NHS IRAS; UK HEI – for multi-site studies; etc) has fully reviewed this project and generated a favourable opinion: Level 1

**This application is complete with the following attachments (tick all that apply):**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Advert/flyer | Caldicott application stating what data was requested | Caldicott signed approval | | Consent form/s |
| Data collection tools (e.g. interview guides) | Debrief with signposting | IRAS application | IRAS opinion letter | NGO or local authority letters |
| Participant Information Sheet/s | Participant Information Sheet (young person version) | R&D application | R&D approval | Researcher Checklist (C-19) |
| Risk assessment | Standardised recruitment email | Sponsorship Letter OR Email to confirm no sponsorship needed / statement explaining why sponsorship is not needed. | | |

|  |
| --- |
| Other attachments (please specify): |

|  |
| --- |
| **To be completed by primary investigator or project supervisor** |
| **By signing this front sheet, I confirm that I have prepared and/or reviewed this ethics application and related documents in accordance with ethical guidelines. I also confirm I have checked that all relevant sections of the application form are completed and relevant documents are attached.**  **Supervisor or/PI Signature:**  **Student signature:**  **Date:** |

On completion, this Word document along with the relevant attachments should be submitted to [ethics.hiss@ed.ac.uk](mailto:ethics.hiss@ed.ac.uk).

Note: **Please note all undergraduate and MSc applications MUST been signed and submitted by the project supervisor.**

Contents

[LEVEL 1 and 2 – Confidentiality and Handling of Data 5](#_Toc64558010)

[Section 1: Introduction 5](#_Toc64558011)

[Section 2: Security-sensitive material 9](#_Toc64558012)

[Section 3: Copyright 10](#_Toc64558013)

[Section 4: Good conduct in collaborative research 11](#_Toc64558014)

[Section 5: Good conduct in publication practice 12](#_Toc64558015)

[LEVEL 2 ONLY – Participant Risk and Information 13](file:///C:\Users\sahonen\Desktop\Research%20Ethics%20Application%20Front%20Sheet.docx#_Toc64558016)

[Section 6: Potential risks to participants and researchers 13](#_Toc64558017)

[Section 7: Participants and data subjects. 16](#_Toc64558018)

[Section 8: Participant or data subject information and consent 19](#_Toc64558019)

|  |
| --- |
| ***This section is to be completed after review only*** |
| **ISSUES ARISING FROM THE PROPOSAL – to be completed by Ethics Reviewer** |
| Thank you for your application. The review process has generated the following queries regarding your application. Please address the following items, and provide a note underneath each comment letting us know how you have addressed them:  OR  Thank you for your application. We have completed the review process and can provide a favourable opinion.  **Signature:**  **Position:**  **Date:** |
| **APPLICANT’S SIGNATURE FOLLOWING REVISIONS – to be completed by applicant** |
| I confirm that I have addressed all of the queries generated during the ethical review process of my application. I have outlined in the box above underneath each comment how each request was addressed and/or provided further clarification.  **Supervisor/PI Signature:**  **Student signature:**  **Date:** |
| **CONCLUSION TO ETHICAL REVIEW – to be completed by Ethics Lead** |
| The applicant’s response to our request for further clarification or changes has now satisfied the requirements for ethical practice and the application has therefore been given a favourable opinion.  OR  Thank you for providing responses to our comments. Some outstanding questions remain:  **Signature:**  **Position:**  **Date:**  that a favourable opinion has been provided for this project (for example as an attachment to MSc dissertations).  NOTE: Once reviewed please include the page on which this box appears as a formal document demonstrating that favourable opinion has been provided for this project (for example as an attachment to MSc dissertations). |

|  |
| --- |
| **If you are applying for amendments to a previously reviewed and processed project, please use the below form to detail the amendments you wish to make:** |
| ***This section is to be completed for amendments only*** |
| **AMENDMENT/S: REQUEST FOR APPROVAL – to be completed by applicant** |
| I would like to apply for the following amendments to this previously processed project which had generated a favourable opinion:  **Supervisor/PI Signature:**  **Student signature:**  **Date:** |
| **CONCLUSION TO ETHICAL REVIEW OF AMENDMENT – to be completed by Ethics Lead** |
| The requested amendment satisfies the requirements for ethical practice and it has therefore received a favourable opinion.  OR  Additional information is required related to:  **Signature:**  **Position:**  **Date:**  NOTE: Once reviewed please include the page on which this box appears as a formal document demonstrating that favourable opinion has been provided for this project (for example as an attachment to MSc dissertations). |

# LEVEL 1 and 2 – Confidentiality and Handling of Data

# Section 1: Introduction

**External Research Ethics Approval:**

**Does your research project require the approval of any other institution and/or ethics committee, nationally or internationally?**

Note: It is each researcher’s responsibility to check whether their project requires Sponsorship, Caldicott Approval, R&D approval, and/or IRAS (see <https://www.ed.ac.uk/health/research/ethics-and-integrity>). The principal investigator is responsible for ensuring compliance with any additional ethical requirements that might apply, and/or for compliance with any additional requirements for review by external bodies.

This research project does not require external ethics approval.

OR

*If you require external approval, please state the name of the review body:*

IRAS (NHS research ethics)  Local Authority  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |
| --- |
| **NB**: If you require external approval from IRAS/NHS/Caldicott, **you must have external approval before submitting your application for School of Health in Social Science Research Ethics approval**. You can only submit your application to us once external approval has been obtained, and you must include all documentation including your application to and approval of external approval as an attachment.  If you require approval from a **local authority**, you must first receive ethics approval from the School of Health in Social Science Research Ethics Committee, before submitting your application to the local authority. |

**Q1. Project summary**

**Please provide a brief summary of your proposed study. Do not exceed 1500 words. Our interest is in areas of your methodology where ethical issues may arise so please focus your detail on areas such as recruitment, consent, describing your participants and the nature of their involvement, and data handling.**

|  |
| --- |
|  |

**Q2. Will you collect or use NHS data?**

Yes  No

*If “yes” – what NHS data will you collect or use?*

|  |
| --- |
|  |

**Q3. What information about participants/data subjects will you collect and/or use?**

|  |
| --- |
|  |

**Q4. What training will staff who have access to the data receive on their responsibilities for its safe handling? Have all staff and students who have access completed the mandatory data protection training on the self-enrolment page of Learn?**

|  |
| --- |
|  |

**Q5. Will the information include special categories of personal data (health data, data relating to race or ethnicity, to political opinions or religious beliefs, trade union membership, criminal convictions, sexual orientations, genetic data and biometric data)?**

Yes  No

*If “yes” – Explain what safeguards e.g. technical or organisational you have in place; including any detailed protocols if this requires special and/or external processing, storage, and analysis.*

|  |
| --- |
|  |

**Q6. Please indicate how your research is in the public interest:**

Your research is proportionate

Your research is subject to a governance framework

Research Ethics Committee (REC) review (does not have to be a European REC)

Peer review from a funder

Confidentiality Advisory Group (CAG) recommendation for support in England and Wales or support by the Public Benefit and Privacy Panel (PBPP) for Health and Social Care in Scotland

Other

**Q7. It is essential that you identify, and list all risks to the privacy of research participants. You will then need to consider the likelihood of the risks actually manifesting and the severity of harm if the risks actually manifest.**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Risk** | **Likelihood of risk manifesting** | | | **Severity of harm** | | |
| **Remote** | **Possible** | **Probable** | **Minimal** | **Significant** | **Severe** |
| Identifiable due to data linkage |  |  |  |  |  |  |
| Identifiable due to low participant numbers |  |  |  |  |  |  |
| Identifiable due to geographical location |  |  |  |  |  |  |
| Identifiable due to transfer of data |  |  |  |  |  |  |
| Identifiable due to access of data |  |  |  |  |  |  |
| *Insert more rows as appropriate* |  |  |  |  |  |  |

*Please use this text box to record any other risks and the likelihood of them occurring, along with the severity of harm. Please also use this when dealing with secondary data.*

|  |
| --- |
|  |

*Please identify measures you could take to reduce or eliminate risks identified as possible/significant or probable/severe.*

|  |
| --- |
|  |

**Q8. Will information containing personal, identifiable data be transferred to, shared with, supported by, or otherwise available to third parties outside the University?**

Yes  No

*If “yes” - Please explain why this necessary and how the transfer of the information will be made secure. If the third party is based outside the European Economic Area please obtain guidance from the Data Protection Officer.*

|  |
| --- |
|  |

**Q9. Other than the use by third parties, will the data be used, accessed or stored away from University premises?**

Yes  No

*If “yes” - Describe the arrangements you have put in place to safeguard the data from accidental or deliberate access, amendment or deletion when it is not on University premises, including when it is in transit, and (where applicable) it is transferred outside the EEA.*

|  |
| --- |
|  |

**Q10. Will feedback of findings be given to your research project participants or data subjects?**

Yes  No

*If “yes” - How and when will this feedback be provided?*

|  |
| --- |
|  |

*If “no” - Please provide rationale for this.*

|  |
| --- |
|  |

**Q11. How do you intend to use/disseminate the results of your research project?**

|  |
| --- |
|  |

# Section 2: Security-sensitive material

**The Terrorism Act (2006) outlaws the dissemination of records, statements and other documents that can be interpreted as promoting or endorsing terrorist acts.**

**Q12. Does your research involve the storage on a computer of any such records, statements or other documents?**

Yes  No (if you answered no to this question please jump to section 3)

*If “yes” - Please type 'Yes' to indicate that you agree to store all documents on that file store*

|  |
| --- |
|  |

Q**13. Might your research involve the electronic transmission (for example, as an email attachment) of such records or statements?**

Yes  No

*If “yes” - Please type ‘Yes’ to indicate that you agree not to transmit electronically to any third party documents stored in the file store*

|  |
| --- |
|  |

**Q14. Will your research involve visits to websites that might be associated with extremist, or terrorist, organisations?**

Yes  No

*If “no”, please proceed to Question 15.*

*If “yes” - You are advised that such sites may be subject to surveillance by the police. Accessing those sites from University IP addresses might lead to police enquiries. Please type ‘Yes’ to acknowledge that you understand this risk*

|  |
| --- |
|  |

By submitting to the ethics process, you accept that your School Research Ethics Officer and the convener of the University’s Compliance Group will have access to a list of titles of documents (but not the contents of documents) in your document store. *Please type ‘Yes’ to acknowledge that you accept this.*

|  |
| --- |
|  |

Please confirm that you have contacted your School Research Ethics Officer to discuss security-sensitive material by ticking ‘Yes’

Yes, I have contacted my School’s Research Ethics Officer

No, I have not contacted my School’s Research Ethics Officer

# Section 3: Copyright

**Q15. Does your project require use of copyrighted material?**

Yes  No

*If “yes” please give further details*

|  |
| --- |
|  |

# Section 4: Good conduct in collaborative research

**Q16. Does your project involve working collaboratively with other academic partners?**

Yes  No (if you answered no to this question please jump to section 5)

*If “yes” - Is there a formal agreement in place regarding a collaborative relationship with the academic partner(s)?*

|  |
| --- |
|  |

*If “no” - Please explain why there is no formal agreement in place*

|  |
| --- |
|  |

**Q17. Does your project involve working collaboratively with other non-academic partners?**

Yes  No

*If “yes” - Is there a formal agreement in place regarding a collaborative relationship with the non-academic partner(s)?*

|  |
| --- |
|  |

*If “no” - Please explain why there is no formal agreement in place.*

|  |
| --- |
|  |

**Q18. Does your project involve employing local field assistants (including guides/translators)?**

Yes  No

*If “yes” - Is there a formal agreement in place regarding the employment of local field assistants (including guides and translators)?*

|  |
| --- |
|  |

*If “no” - Please explain why there is no formal agreement in place*

|  |
| --- |
|  |

**Q19. Will care be taken to ensure that all individuals involved in implementing the research adhere to the ethical and research integrity standards set by the University of Edinburgh?**

Yes  No

*If “no” - Please explain why care will not be taken*

|  |
| --- |
|  |

**Q20. Have you reached agreement relating to intellectual property?**

Yes  No

*If “no” - Please explain why you have not reached agreement*

|  |
| --- |
|  |

# Section 5: Good conduct in publication practice

In publication and authorship, as in all other aspects of research, researchers are expected to follow the University’s guidance on [integrity](https://research-office.ed.ac.uk/research-integrity/university-ethics-policy) and [research publications and copyright policy](https://www.ed.ac.uk/information-services/about/policies-and-regulations/research-publications). By ticking yes, you confirm that full consideration of the items described in this Section will be addressed as applicable

Yes  No

**If you intend to collect new data, please continue completing the Level 2 application in the next page.**

**If you are NOT collecting any new data, you have now completed the Level 1 application. Please submit this document alongside all attachments to** [**ethics.hiss@ed.ac.uk**](mailto:hiss.ethics@ed.ac.uk) **.**

# LEVEL 2 ONLY – Participant Risk and Information

**The following Sections are to be completed if you are collecting new data. Please do not complete it if you are using existing data.**

# Section 6: Potential risks to participants and researchers

**Q21. Is your research project likely or possible to induce any psychological stress or discomfort in the participants or others, indirectly associated with the research?**

Yes  No

*If “yes” state the types of risk and what measures will be taken to deal with such problems*

|  |
| --- |
|  |

**Q22. Does your research project require any physically-invasive or potentially physically harmful procedures?**

Yes  No

*If “yes” give details and outline procedures to be put in place to deal with potential problems.*

|  |
| --- |
|  |

**Q23. Does your research project require the use of privacy-invasive technology, such as CCTV, biometrics, facial recognition, vehicle tracking software?**

Yes  No

*If “yes” - Give details and outline procedures to be put in place to deal with potential problems.*

|  |
| --- |
|  |

**Q24. Does your research project involve the investigation of any illegal behaviour or activities?**

Yes  No

*If “yes” - Give details of any illegal behavior or activities you may investigate*

|  |
| --- |
|  |

**Q25. Is it possible that your research project will lead to awareness or the disclosure of information about child abuse or neglect?**

Yes  No

*If “yes” - Indicate the likelihood of disclosure and the procedures to be followed if you become aware that a child has been or may be at risk of harm*

|  |
| --- |
|  |

**Q26. Is it likely that dissemination of research findings or data could adversely affect participants or others indirectly associated with the research?**

Yes  No

*If “yes” - Describe the potential risk for participants/data subjects of this use of the data. Outline any steps that will be taken to protect participants.*

|  |
| --- |
|  |

**Q27. Could participation in this research adversely affect participants and others associated with the research in any other way?**

Yes  No

*If “yes” - Describe the possible adverse effects and the procedures to be put in place to protect against them.*

|  |
| --- |
|  |

**Q28. Is this research expected to benefit the participants, directly or indirectly?**

Yes  No

*If “yes” - Give details of how this research is expected to benefit the participants.*

|  |
| --- |
|  |

**Q29. Will the true purpose of the research be concealed from the participants/data subjects?**

Yes  No

*If “yes” - Explain what information will be concealed and why.*

|  |
| --- |
|  |

**Q30. Will participants/data subjects be debriefed at the conclusion of the study?**

Yes  No

*If “no” – Why will participants / data subjects not be debriefed?*

|  |
| --- |
|  |

**Q31. At any stage in this research could researchers’ safety be compromised, or could the research induce emotional distress in the researchers?**

Yes  No

*If “yes” - Give details and outline procedures to be put in place to deal with potential problems.*

|  |
| --- |
|  |

**Please tick to confirm you agree with the following:**

I will adhere to School guidance on risk assessment and health and safety and will seek advice on project and travel insurance prior to project commencement.

I agree

I do not agree

Not applicable

# Section 7: Participants and data subjects.

**Q32. How many participants or data subjects are expected to be included in your research project?**

|  |
| --- |
|  |

**Q33. What criteria will be used in deciding on the inclusion and exclusion of participants/data subjects in your research project?**

|  |
| --- |
|  |

**Q34. Are any of the participants or data subjects likely to be under 16 years of age?**

Yes  No

*If “yes” - Explain and describe the measures that will be used to protect and/or inform participants/data subjects.*

|  |
| --- |
|  |

**Q35. Are any of the participants or data subjects likely to be children in the care of a Local Authority?**

Yes  No

*If “yes” - Explain and describe the measures that will be used to protect and/or inform participants/data subjects.*

|  |
| --- |
|  |

**Q36. Are any of the participants or data subjects likely to be known to have additional support needs?**

Yes  No

*If “yes” - Explain and describe the measures that will be used to protect and/or inform participants/data subjects.*

|  |
| --- |
|  |

**Q37. In the case of participants with additional support needs, will arrangements be made to ensure informed consent?**

Yes  No  N/A

*If “yes” – What arrangements will be made?*

|  |
| --- |
|  |

*If “no” – Please explain why not*

|  |
| --- |
|  |

**Q38. Are any of the participants or data subjects likely to be physically or mentally ill?**

Yes  No

*If “yes” - Explain and describe the measures that will be used to protect and/or inform participants/data subjects.*

|  |
| --- |
|  |

**Q39. Are any of the participants or data subjects likely to be vulnerable or likely exposed to harm in other ways?**

Yes  No

*If “yes” - Explain and describe the nature of the vulnerability and the measures that will be used to protect and/or inform participants/data subjects.*

|  |
| --- |
|  |

**Q40. Are any of the participants or data subjects likely to be unable to communicate in the language in which the research is conducted?**

Yes  No

*If “yes” - Explain and describe the measures that will be used to protect and/or inform participants/data subjects.*

|  |
| --- |
|  |

**Q41. Are any of the participants or data subjects likely to be in a relationship (i.e., professional, student-teacher, other dependent relationship) with the researchers?**

Yes  No

*If “yes” - Explain and describe the measures that will be used to protect and/or inform participants/data subjects.*

|  |
| --- |
|  |

**Q42. Are any of the participants or data subjects likely to have difficulty in reading and/or comprehending any printed material distributed as part of the study?**

Yes  No

*If “yes” - Explain and describe the measures that will be used to protect and/or inform participants/data subjects.*

|  |
| --- |
|  |

**Q43. Describe how the sample will be recruited.**

|  |
| --- |
|  |

**Q44. Will participants receive any financial or other material benefits as a result of participation?**

Yes  No

*If “yes” - What benefits will be offered to participants and why?*

|  |
| --- |
|  |

# Section 8: Participant or data subject information and consent

**Q45. Will written or oral consent be obtained from all participants or data subjects?**

Yes  No

*If “yes” – attach participant information sheet and consent form and detail the process you will follow.*

*If “no” – explain why not and what process you will follow regarding consent, or if consent cannot or should not be sought for some reason, please provide a clear case and rationale for this (e.g. in international contexts where speaking to foreign researchers is prohibited).*

|  |
| --- |
|  |

**Q46. Have you made arrangements to tell participants what information you will hold about them and for how long?**

Yes  No

*If “yes” - what arrangements have been made?*

|  |
| --- |
|  |

*If “no” – why not?*

|  |
| --- |
|  |

**Q47. Have you made arrangements to tell participants whether you will disclose the information to other organisations?**

Yes  No  N/A

*If “yes” - What arrangements have been made?*

|  |
| --- |
|  |

*If “no” – why not?*

|  |
| --- |
|  |

**Q48. Have you made arrangements to tell participants whether you will combine that information with other data?**

Yes  No  N/A

*If “yes” - What arrangements have been made?*

|  |
| --- |
|  |

**Q49. In the case of children participating in the research, will the consent or assent of parents be obtained?**

Yes  No  N/A

*If “yes” - Explain how this consent or assent will be obtained*

|  |
| --- |
|  |

*If “no” – Please explain why you won’t be obtaining consent*

|  |
| --- |
|  |

**Q50. Will the consent or assent of children participating in the research be obtained?**

Yes  No  N/A

*If “yes” - Explain how this consent or assent will be obtained*

|  |
| --- |
|  |

*If “no” – Please explain why not*

|  |
| --- |
|  |

**Q51. In the case of participants who are not proficient in the language in which the research is conducted, will arrangements be made to ensure informed consent?**

Yes  No  N/A

*If “yes” – What arrangements will be made?*

|  |
| --- |
|  |

*If “no” – Please explain why not*

|  |
| --- |
|  |

**Q52. Does the activity involve using cookies or tracking individual’s activity on a website or the Internet in general?**

Yes  No

*If “yes” – Describe the arrangements you have put in place to obtain informed consent for the use of these tools*

|  |
| --- |
|  |

**You have now completed the Level 2 application. Please submit this document alongside all attachments to** [**ethics.hiss@ed.ac.uk**](mailto:hiss.ethics@ed.ac.uk) **.**