#

# **University of Edinburgh, School of Health in Social Science**

# **Research Ethics, Integrity and Governance**

The forms required when seeking ethical approval in the School of Health and Social Sciences have now been merged into this single electronic document.  The sections you are required to complete will depend on the nature of your application.  Please start to complete the form from the beginning and proceed as guided.  On completion the *entire*document should be submitted electronically to your section’s ethics administrator using the email addresses detailed on the final page.

Applications submitted without appropriate documentation will be returned.

Please work your way through this form, reading the questions and accompanying information carefully. Sections highlighted in yellow are mandatory, so you must answer all the questions in these sections.

Aside from the mandatory questions you won’t always need to answer all of the questions in the form. Section 1 “your project details” includes a set of filter questions that determine the rest of the questions you need to answer. Please read the notes carefully to make sure you answer the right questions. The notes contain hyperlinks so you can jump directly to the relevant section.

Sections highlighted in yellow are **mandatory**. These must be completed for every application.

[Section 1:](#_SECTION_1:_INTRODUCTION) Introduction

[Section 2:](#_SECTION_2:_Your) Your project details

[Section 3:](#_SECTION_3:_Description) Description of the research

[Section 4:](#_SECTION_4:_Potential) Potential risks to participants and researchers

[Section 5:](#_SECTION_5:_Participants_1) Participants and data subjects

[Section 6:](#_Section_6:_Participant) Participants or data subject information and consent

[Section 7:](#_SECTION_7:_Confidentiality) Confidentiality and handling of data

[Section 8:](#_SECTION_8:_Security-sensitive) Security sensitive material

[Section 9:](#_Section_9:_Copyright) Copyright

[Section 10:](#_Section_10:_Good) Good conduct in collaborative research

[Section 11:](#_Section_11:_Good) Good conduct in publication research

***SECTION 1: Introduction***

This is a:

New application for ethical approval – first submission [ ]

A resubmission following reviewer comments [ ]

A resubmission with requested amendments [ ]

Please select your School:

[ ]  School of Health in Social Science

Please select your subject area

[ ]  CPASS

[ ]  Clinical Psychology

[ ]  Nursing Studies

It is each researcher’s responsibility to check whether their project requires Sponsorship, Caldicott Approval, R&D approval, and/or IRAS. <https://www.ed.ac.uk/health/research/ethics/sponsorship-and-governance>

**If the project requires any of these, these need to be secured prior to submitting this application.**

Please tick the relevant box before proceeding:

I have checked and this project does not require Sponsorship, Caldicott, R&D and/or IRAS approval [ ]

My project requires Sponsorhip [ ]  Sponsorship letter attached [ ]

My project requires Caldicott approval [ ]  Caldicott approval letter/e-mail attached [ ]

My project requires R&D approval [ ]  R&D approval letter/e-mail attached [ ]

My project requires IRAS approval [ ]  IRAS approval letter/e-mail attached [ ]

## External Research Ethics Approval

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

*Please state the name of the review body and the current status of your application (for example, submitted, approved, deferred, or rejected)? Please include any known submission / approval timelines.*

|  |
| --- |
|  |

# **SECTION 2: Your project details**

## 2.1 Project details

Your name:

Please enter your project title:

Proposed Project Start Date:

Proposed Project End Date:

## Q1. Are you a member of staff or a student?

[ ]  Staff member

Supplementary questions for staff members only:

*List the names and institutions of any Co-Investigators working with you on the project.*

|  |
| --- |
|  |

[ ]  Student

Supplementary questions for students only:

*What type of student are you?*

|  |
| --- |
|  |

*Please provide your course title or programme name*

|  |
| --- |
|  |

 *Who is your supervisor?*

|  |
| --- |
|  |

## Q2. Please indicate any external ethical guidance your project has to adhere to. For example, the British Psychological Society (BPS), the British Academy, the British Association of Sport and Exercise Sciences (BASES)

|  |
| --- |
|  |

## 2.2 Participants

## Q3. Will you be collecting or generating any new data (including autoethnographic writings)?

[ ]  Yes

[ ]  No

## Q4. Will you be extracting, re-coding or using existing data that contains sensitive information (i.e., identifiable information)?

[ ]  Yes

[ ]  No

If the answers to both Q3 and Q4 are ‘no’ you are not required to complete:

[Section 4:](#_SECTION_4:_Potential) Potential risks to participants and researchers

[Section 5:](#_SECTION_5:_Participants) Participants and data subjects

[Section 6:](#_Section_6:_Participant) Participant or data subject information and consent

## 2.3 Security-Sensitive Material

## Q5. Does your research project fit into any of the following security-sensitive categories?

[ ]  Your research project is commissioned by the military.

[ ]  Your research project is commissioned under an EU security cell.

[ ]  Your research project involves the acquisition of security clearances.

[ ]  Your research project concerns groups which may be construed as terrorist or extremist

If you answer ‘yes’ to any of the questions above you must complete [Section 8 Security Sensitive Material](#_SECTION_8:_Security-sensitive). You must answer all questions in the section.

## 2.4 Good Conduct in Collaborative Research

## Q6. Will your research project involve collaborative work?

[ ]  Yes

[ ]  No

Selecting "Yes" to this question means you must complete [Section 10 "Good conduct in collaborative research"](#_Section_10:_Good) later in the form. You must answer all questions in the section.

## 2.5 Project Funding

## Q7. Is funding required for your research project? (To be completed by staff only)

*Please indicate how the project will be financially supported.*

|  |
| --- |
|  |

## 2.6 Knowledge Exchange and Impact

## Q8. Will there be any knowledge exchange and impact activities associated with this project? (To be completed by staff only)

|  |
| --- |
|  |

# **2.7 Consultancy Potential**

## Q9. Could your research project lead to potential consultancy activities in the future? (To be completed by staff only)

|  |
| --- |
|  |

# **SECTION 3: Description of the research**

## Q10: Please use the box below to describe your research; including a background summary, rationale, research questions and hypotheses, methodology, procedures. If you have identified ethical considerations that are not addressed in other parts of the form, please outline and discuss them here.

|  |
| --- |
|  |

# **SECTION 4: Potential risks to participants and researchers**

## Q11. 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*

|  |
| --- |
|  |

## Q12. 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.*

|  |
| --- |
|  |

## Q13. 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.*

|  |
| --- |
|  |

## Q14. 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*

|  |
| --- |
|  |

## Q15. 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*

|  |
| --- |
|  |

## Q16. 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.*

|  |
| --- |
|  |

## Q17. 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.*

|  |
| --- |
|  |

## Q18. 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.*

|  |
| --- |
|  |

## Q19. 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.*

|  |
| --- |
|  |

## Q20. Will participants/data subjects be debriefed at the conclusion of the study?

[ ]  Yes

[ ]  No

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

|  |
| --- |
|  |

## Q21. 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 5: Participants and data subjects. For autoethnographic research also include those who may feature in your writings.**

## Q22. How many participants or data subjects are expected to be included in your research project?

|  |
| --- |
|  |

## Q23. What criteria will be used in deciding on the inclusion and exclusion of participants/data subjects in your research project?

|  |
| --- |
|  |

## Q24. 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.*

|  |
| --- |
|  |

## Q25. 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.*

|  |
| --- |
|  |

## Q26. 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.*

|  |
| --- |
|  |

**Q27. In the case of participants with additional support needs, will arrangements be made to ensure informed consent?**

[ ]  **Yes**

[ ]  **No**

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

|  |
| --- |
|  |

**If “no” – Please explain why not**

|  |
| --- |
|  |

## Q28. 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.*

|  |
| --- |
|  |

## Q29. 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.*

|  |
| --- |
|  |

## Q30. 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.

|  |
| --- |
|  |

## Q31. 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.*

|  |
| --- |
|  |

## Q32. 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.*

|  |
| --- |
|  |

## Q33. Describe how the sample will be recruited.

|  |
| --- |
|  |

## Q34. 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 6: Participant or data subject information and consent**

## Q35. Will written consent be obtained from all participants or data subjects?

[ ]  Yes

[ ]  No

*If “yes” – attach participant information sheet and consent form*

*If “no” – explain why not and how consent is obtained (e.g. orally), and/or if consent cannot or should not be sought for some reason, please provide a clear case and rationale for this*

|  |
| --- |
|  |

## Q36. 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?*

|  |
| --- |
|  |

## Q37. Have you made arrangements to tell participants whether you will disclose the information to other organisations?

[ ]  Yes

[ ]  No

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

|  |
| --- |
|  |

## Q38. Have you made arrangements to tell participants whether you will combine that information with other data?

[ ]  Yes

[ ]  No

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

|  |
| --- |
|  |

## Q39. In the case of children participating in the research, will the consent or assent of parents be obtained?

[ ]  Yes

[ ]  No

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

## Q40. Will the consent or assent of children participating in the research be obtained?

[ ]  Yes

[ ]  No

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

|  |
| --- |
|  |

*If “no” – Please explain why not*

|  |
| --- |
|  |

## Q41. 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

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

|  |
| --- |
|  |

*If “no” – Please explain why not*

|  |
| --- |
|  |

## Q42. 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?

|  |
| --- |
|  |

# **SECTION 7: Confidentiality and handling of data**

## Q43. What information about participants/data subjects will you collect and/or use?

|  |
| --- |
|  |

## Q44. Will you collect or use NHS data?

[ ]  Yes

[ ]  No

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

|  |
| --- |
|  |

## Q45. What training will staff who have access to the data receive on their responsibilities for its safe handling? Have all staff who have access completed the mandatory data protection training on the self-enrolment page of Learn?

|  |
| --- |
|  |

## Q46. 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.*

|  |
| --- |
|  |

If you answered “no” to this question, please skip Q56 and continue answering the rest of the questions..

## Q47. 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

## Q48. 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 identify measures you could take to reduce or eliminate risks identified as possible/significant or probable/severe.*

|  |
| --- |
|  |

## Q49. 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.*

|  |
| --- |
|  |

## Q50. 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.*

|  |
| --- |
|  |

## Q51. 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.*

|  |
| --- |
|  |

## Q52. How do you intend to use/disseminate the results of your research project?

|  |
| --- |
|  |

# **SECTION 8: 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.**

## Q53. Does your research involve the storage on a computer of any such records, statements or other documents?

[ ]  Yes

[ ]  No

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

|  |
| --- |
|  |

## Q54. Might your research involve the electronic transmission (for example, as an email attachment) of such records or statements?

[ ]  Yes

[ ]  No

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

|  |
| --- |
|  |

## Q55. Will your research involve visits to websites that might be associated with extreme, or terrorist, organisations?

[ ]  Yes

[ ]  No

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 acknowledge that you understand this risk by ticking ‘Yes’

[ ]  Yes

[ ]  No

By submitting to the ethics process, you accept that your School Research Ethics Officer and the convenor 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 acknowledge that you accept this by ticking 'Yes'

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 9: Copyright**

## Q56. Does your project require use of copyrighted material?

[ ]  Yes

[ ]  No

*If “yes” please give further details*

|  |
| --- |
|  |

# **Section 10: Good conduct in collaborative research**

## Q57. Does your project involve working collaboratively with other academic partners?

[ ]  Yes

[ ]  No

*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?*

|  |
| --- |
|  |

## Q58. 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.

|  |
| --- |
|  |

## Q59. 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

|  |
| --- |
|  |

## Q60. 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*

|  |
| --- |
|  |

## Q61. Have you reached agreement relating to intellectual property?

[ ]  Yes

[ ]  No

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

|  |
| --- |
|  |

# **Section 11: 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://www.ed.ac.uk/governance-strategic-planning/research/research-integrity/policies).

By ticking yes, you confirm that full consideration of the items described in this section will be addressed as applicable

[ ]  Yes

[ ]  No

|  |
| --- |
| Subsequent to submission of this form, **both the applicant and their supervisor should review any alterations in the proposed methodology of the project.** If the change to methodology results in a change to any answer on the form, then a resubmission to the Ethics subgroup is **required.** 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. |

 ALL forms should be submitted in electronic format. Digital signatures or scanned in originals are acceptable. The applicant should keep a copy of all forms for inclusion in their thesis.

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

**Applicant’s**  Name Applicant’s Signature Date signed

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

\*Supervisor Signature[[1]](#footnote-1) Supervisor Name Date

\*NOTE to Supervisor: Ethical review will be based only on the information contained in this form. If countersigning this check-list as truly warranting all ‘No’ answers, you are taking responsibility, on behalf of the HSS and UoE, that the research proposed truly poses no ethical risks.

|  |
| --- |
| **ISSUES ARISING FROM THE PROPOSAL** |
| The applicant should respond to these comments in section below.Signature: Position: Date:  |
| **APPLICANT’S RESPONSE (If required)** |
| Signature: Date:  |
| **CONCLUSION TO ETHICAL REVIEW (if required)** |
| The applicant’s response to our request for further clarification or amendments has now satisfied the requirements for ethical practice and the application has therefore been approved.Signature:Position: Date: |

|  |
| --- |
| **AMENDMENT/S: REQUEST FOR APPROVAL** |
| Signatures: Date:  |
| **CONCLUSION TO ETHICAL REVIEW OF AMENDMENT** |
| The applicant’s response to our request for further clarification or amendments has now satisfied the requirements for ethical practice and the application has therefore been approved.Signature:Position: Date: |

Acronyms / Terms Used

NHS: National Health Service

SHSS: School of Health in Social Science

IRAS: Integrated Research Applications System

Section: The SHSS is divided into Sections or subject areas, these are; Nursing Studies, Clinical Psychology, C-PASS.

**Ethics Administrators**

Nursing Studies: nursing@ed.ac.uk

Counselling, Psychotherapy and Applied Social Science: CPASS.ethics@ed.ac.uk

Clinical Psychology: Submitting.Ethics@ed.ac.uk

MA in Health, Science and Society: mahssug@ed.ac.uk

1. Not required for staff applications [↑](#footnote-ref-1)