**Annex B:** **Research Ethics Review**

This form should be completed for every research project that involves human participants or the use of information relating to directly identifiable individuals.

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| **PART I - Checklist** | | | | | | |
| The Checklist is designed to identify the nature of any ethical issues raised by the research.  This checklist must be completed before potential participants are approached to take part in any research. | | | | | | |
| **1. Name of Researcher:** | | | | | | |
|  | Status *(mark with an ‘X’ as appropriate)* | Undergraduate student |  | Masters student | |  |
| Research degree student |  | Staff | |  |
| Email |  | Telephone number |  | | |
| Department |  | | | | |
| **2. Student Details if applicable** | | | | | | |
|  | Degree programme: |  | | | | |
| Supervisor’s name: |  | Supervisor’s email: | |  | |
| Supervisor’s department: |  | | | | |
| **3. Title of the proposal and brief abstract** | | | | | | |
| *(150-200 words – your abstract should outline in non-technical language the purpose of the research and the methods that will be used.)* | | | | | | |
| **4. Funding** | | | | | | |
| Is it proposed that the research will be funded? If so by whom? | | | | | | |

|  | | *Please mark an X in the appropriate right-hand column/box* | | **Yes** | | **No** | **Not certain** | |
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| **5. Research that *may* need to be reviewed by an external Ethics Committee** | | | | | | | | |
| i | | Will the study require Health Research Authority approval? *(*[*See Note 1*](#_NOTES)*)* | |  | |  |  | |
| ii | | Does the study involve participants lacking capacity to give informed consent? *(*[*See Note 2)*](#_NOTES) | |  | |  |  | |
| iii | | Is there any other reason why the study may need to be reviewed by another external Ethics Committee? | |  | |  |  | |
|  | | **If you have answered Yes to any of the questions in section 5, go to** [**Part II, C**](#_PART_II:_Self) (there is no need to complete the rest of the Checklist) | | | | | | |
| **6**. **Consent** | | | | | | | | |
| i | | Does the study involve participants who are potentially or in any way vulnerable or who may have any difficulty giving meaningful consent to their participation or the use of their information? *(*[*See Note 3*](#_NOTES)*)* | |  | |  |  | |
| ii | | Are participants to be enlisted in the study without their knowledge and consent? (e.g. via covert observation of people in public places) | |  | |  |  | |
| iii | | Will the study require the co-operation of a gatekeeper for initial access to the groups or individuals to be recruited? | |  | |  |  | |
| **7. Research Design / Methodology** | | | | | | | | |
| i | | Does the research methodology involve the use of deception? *(*[*See Note 4*](#_NOTES)*)* | |  | |  |  | |
| ii | | Are there any significant concerns regarding the design of the research project? For example:   * where research intrudes into the private sphere or delves into some deeply personal experience; * where the study is concerned with deviance or social control; * where the study impinges on the vested interests of powerful persons or the exercise of coercion or domination; or * where the research deals with things that are sacred to those being studied that they do not wish profaned. | |  | |  |  | |
| iii | | If the proposed research relates to the provision of social or human services is it feasible and/or appropriate that service users or service user representatives should be in some way involved in or consulted upon the development of the project? | |  | |  |  | |
| **8. Financial Incentives** | | | | | | | | |
| i | | Are there payments to researchers/participants that may have an impact on the objectivity of the research? | |  | |  |  | |
| ii | | Will financial inducements (other than reasonable expenses and compensation for time) be offered to participants? | |  | |  |  | |
| **9. Research Subjects** | | | | | | | | |
| i | | Could the study induce unacceptable psychological stress or anxiety or cause harm or negative consequences beyond the risks encountered in normal life?  Will the study involve prolonged or repetitive testing? | |  | |  |  | |
| ii | | Will the study involve discussion of sensitive topics? For example (but not limited to): sexual activity, illegal behaviour, experience of violence or abuse, drug use, etc.). (Please refer to the Research Ethics Policy, § 13). | |  | |  |  | |
| iii | | Are drugs, placebos or other substances to be administered to the study participants or will the study involve invasive, intrusive or potentially harmful procedures of any kind? | |  | |  |  | |
| **10. Confidentiality** | | | | | | | | |
| i | | Will research involve the sharing of data or confidential information beyond the initial consent given? | |  | |  |  | |
| ii | | Will the research involve respondents to the internet, e.g. social media, or other visual/vocal methods | |  | |  |  | |
| iii | | Will the research involve administrative or secure data that requires permission from the appropriate authorities before use? | |  | |  |  | |
| **11. Legal requirements** | | | | | | | | |
|  | | The Data Protection Act 1998 will apply to any data-processing activities entailed by this research. Is there any cause for uncertainty as to whether the research will fully comply with the requirements of the Act? *(*[*See Note 5*](#_NOTES)*)* | |  | |  |  | |
| **12. Dissemination** | | | | | | | | |
|  | | Are there any particular groups who are likely to be harmed by dissemination of the results of this project? | |  | |  |  | |
| **13. Risk to researchers** | | | | | | | | |
|  | Do you have any doubts or concerns regarding your (or your colleagues) physical or psychological wellbeing during the research period? | |  | |  | | |  |

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| PART II: Self certification and/or next steps | | | |
| **A** If, after careful consideration, you have answered **No** to all the questions (whether you are a member of the academic staff or a student), you do not need to complete the questionnaire in Part III, unless you are subject to some external requirement that requires you to seek formal approval from the School's Research Ethics Committee. You should tick Box **A** in the **Self-Certification Section** below, sign as appropriate and submit the form to your Head of Department, Research Centre Director, or their administrations as appropriate. Occasional audits of such forms may be undertaken by the School.  **B** If you have answered **Yes** or **Not certain** to any of the questions in sections 6-13 of the checklist you will need to consider more fully how you plan to deal with the ethical issues raised by your research. Answering the relevant questions in the Questionnaire in Part III below may assist you. Alternatively, your own department or institute may have alternative forms or procedures to assist you. If having done so you are wholly assured that adequate safeguards in relation to the ethical issues raised can and will be put in place, you may tick **Box B** in the Self-certification Section below, sign as appropriate and submit the form to your Head of Department, Research Centre Director, or their administrations as appropriate. Occasional audits of such forms may be undertaken by the School.  **C** If you have answered Yes in section 5 that your research will be subject to an external ethics committee, please tick **Box C** below and send the completed Checklist (questions 1-5) to [research.ethics@lse.ac.uk](mailto:research.ethics@lse.ac.uk). You should submit your research for ethics approval to the appropriate body. Once approval is granted please send a copy of the letter of approval to [research.ethics@lse.ac.uk](mailto:research.ethics@lse.ac.uk).  Students who self-certify their research proposals should do so in consultation with their supervisors.  If you are unable to self-certify your proposed research you should in any event complete the questionnaire in Part III below and complete the **Refer to Research Ethics Committee Section** at the end of the form. | | | |
| **SELF-CERTIFICATION** | | | |
| ***Select A, B or C*** *(delete as appropriate):*  I have read and understood the LSE Research Ethics Policy and the questions contained in the Checklist above and confirm:  **A** that no significant ethical issues are raised by the research, or  **B**  that adequate safeguards in relation to such issues can and will be put in place, or  **C** that the research will be subject to an external ethics review  **Please sign the relevant section below** | | | |
| ***Academic Research Staff*** | | | |
| Summary of any ethical issues identified and safeguards to be taken (expand box as necessary): | | | |
|  | | | |
| I hereby confirm that I have undertaken training and/or have had significant experience in research ethics in the course of my career and/or have sought and obtained expert advice in connection with the ethical aspects of the proposed research: | | | |
| Researcher signature: |  | Date: |  |

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| |  |  |  |  | | --- | --- | --- | --- | | ***Undergraduate/Taught Postgraduate Student/PhD Student*** | | | | | Summary of any ethical issues identified and safeguards to be taken (expand box as necessary): | | | | |  | | | | | I hereby confirm that I have undertaken training in research ethics in the course of my studies and/or that I have consulted and been advised by my supervisor or other expert with regard the ethical implications of my proposed research. | | | | | Student's signature: |  | Date: |  | | Supervisor's signature: |  | Date: |  | | By signing here the supervisor confirms that the student has been advised in relation to any ethical issues raised by her/his research; these have to the best of the supervisor's understanding been adequately addressed in the research design; and the student has been made aware of her/his responsibilities for the ethical conduct of her/his research. | | | | |

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| **Part III - Questionnaire** | | | |
| The questionnaire enables you to explain how the ethical issues relating to your research will be addressed. If you are intending to submit your proposal to the Research Ethics Committee it needs to be completed in full. | | | |
| 1. **Research aims** | | | |
| *Please provide brief (no more than 500 words) details in non-technical language of the research aims, the scientific background of the research and the methods that will be used. This summary should contain sufficient information to acquaint the Committee with the principal features of the proposal. A copy of the full proposal should nonetheless be attached to this document in case it is required for further information.* | | | |
| 1. **Informed consent** | | | |
| i | | Will potential participants be asked to give informed consent in writing and will they be asked to confirm that they have received and read the information about the study? If not, why not?  *Please attach a draft information sheet and/or consent form if this has been prepared* | |
|  | |
| ii | | How has the study been discussed or are there plans to discuss the study with those likely to be involved, including potential participants or those who may represent their views? | |
|  | |
| iii | | Has information (written and oral) about the study been prepared in an appropriate form and language for potential participants? At what point in the study will this information be offered? (see Annex A of the research ethics policy for links to guidance on informed consent). | |
|  | |
| iv | | How will potential participants be informed of whether there will be adverse consequences of a decision not to participate? Or of a decision to withdraw during the course of the study? | |
|  | |
| v | | What provision has been made to respond to queries and problems raised by participants during the course of the study? | |
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| **3. Research design and methodology** | | | |
| i | Where relevant, how does the research methodology justify the use of deception? | | |
|  | | |
| ii | If the proposed research involves the deception of persons in vulnerable groups, can the information sought be obtained by other means? | | |
|  | | |
| iii | How will data be collected and analysed during the project? | | |
|  | | |
| iv | How have the ethical and legal dimensions of the process of collecting, analyzing and storing the data been addressed? | | |
|  | | |
| v | What concerns have been taken into account with regard to the preparation and design of the research project? If agencies, communities or individuals are to be directly affected by the research (e.g. participants, service users, vulnerable communities or relations), what means have you devised to ensure that any harm or distress is minimized and/or that the research is sensitive to the particular needs and perspectives of those so affected? | | |
|  | | | |
| vi | Have you been able to devise a timetable of research? | | |
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| **4. Ethical questions arising from the provision of incentives** | | | |
| i | Are any incentives being offered to participants? | | |
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| **5. Research participants** | | | |
| i | Who do you identify as the participants in the project? Are other people who are not participants likely to be directly impacted by the project? | | |
|  | | |
| ii | What are the specific risks to research participants or third parties? | | |
|  | | |
| iii | If the research involves pain, stress, physical or emotional risk, please detail the steps taken to minimize such effects. | | |
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| **6. Confidentiality** | | | |
| i | | | What arrangements have been made to preserve confidentiality for the participants or those potentially affected, and compliance with data protection law? |
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| **7. Dissemination** | | | |
| i | | | Will the results of the study be offered to those participants or other affected parties who wish to receive them? If so, what steps have been taken to minimize any discomfort or misrepresentation that may result at the dissemination stage. |
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| **8. Risk to researchers** | | | |
| i | | | Are there any risks to researchers? If so, please provide details. |
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| **REFER TO RESEARCH ETHICS COMMITTEE** | | |
| Approval is required by the Research Ethics Committee on one or more of the following grounds (please mark with an 'X' in the appropriate place in the right-hand column): | | |
| a. | Significant ethical issues are raised by the research, including research characterised by one or more of the following features: |  |
|  | (i) Research involving deception of participants, or which is conducted without their full and informed consent at the time the study is carried out or when the data is gathered, or which involves the use of confidential information. |  |
|  | (ii) Research involving more than minimal risk of harm to participants, such as:   * research involving vulnerable groups * research involving personally intrusive or ethically sensitive topics * research involving groups where permission of a gatekeeper is normally required for initial access to members * research which would induce unacceptable psychological stress, anxiety or humiliation or cause more than minimal pain |  |
| b. | The researcher wants to seek the advice of the Research Ethics Committee |  |
| c. | External obligations (for instance, funder requirements, data access requirements) require it |  |
| d. | Research undertaken by a student or member of staff who has not received appropriate training or has insufficient experience in research ethics and has been unable to access appropriate advice or support. |  |

# NOTES

1. If your research involves NHS patients, staff or premises then it will most likely fall under the remit of the NHS Research Ethics Committees; similarly, social care research involving adults, intergenerational social care studies involving adults and children or families and some proposals for social science studies situated in the NHS will fall under the remit of the Social Care Research Ethics Committee. For further guidance see: <http://www.hra.nhs.uk/research-community/before-you-apply/determine-which-review-body-approvals-are-required/>

2. Under the Mental Capacity Act 2005, research involving adults aged 16 or over with learning difficulties or who otherwise ‘lack capacity’ will be subject to approval by an NHS REC if that research is deemed to be ‘intrusive’. For guidance see: <http://www.hra.nhs.uk/resources/research-legislation-and-governance/questions-and-answers-mental-capacity-act-2005/>

3. As general guidance, research participants under the age of 18 may be vulnerable. Also, see Note 2 above re the Mental Capacity Act.

4. Deception can occur at a variety of levels: for example, at one level, experimental methods may depend on participants being deliberately misled as to the true nature or purpose of the research in which they are taking part; at another, covert participant observation may entail an implicit deception as to the true identity and role of the researcher. Deception may be a legitimate and necessary feature of social scientific research, but its use must always be properly justified.

5. Please refer to the School’s guidance on handling the Data Protection aspects of research data: <http://www.lse.ac.uk/intranet/LSEServices/legalAndCompliance/dataProtection/researchData.asp>. Further information about the Data Protection Act 1998 can be found in Annex A of the research ethics policy