Brighton and Sussex Medical School logo


**RGEC Application Form:**

**Taught Student Ethical Review Form for UG and PGT Students**

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| **Project Title** |  | |
| **Email** |  | |
| **Phone No.** |  | |
| **Applicant Status** | Undergraduate / Postgraduate Taught | |
| **Department** |  | |
| **Project Start Date** |  | |
| **Project End Date** |  | |
| **External Funding in place** |  | |
| **External Collaborators** |  | |
| **Funding/Project Title** |  | |
| **Name of Funder** |  | |
| **Project Description**  *This should be a clear, easy to read summary that is as jargon free as possible. It provides an overview of the whole of your research study that readers can understand the first time they read it. Please see INVOLVE (*[*http://www.inv*](http://www.inv)  *o.org.uk/) for further guidance on how to achieve this.* | | |
| **Is this an IRP Project?** | | **Yes / No** |

**» Project Roles**

Please list all investigators in this project's research team. If you specify role "Other" for any investigator please provide further details in the "Comments" field

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| --- | --- | --- | --- | --- | --- |
| **Role** | **Name** | **Email** | **Phone** | **Institution** | **Comments** |
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**BSMS High/Standard Risk Ethical Review Checklist**

The following questions appear in the online ethical review application system in Sussex Direct for applying for ethics review to the BSMS Research Governance and Ethics Committee (RGEC), or BSMS School Research Ethics Officer (SREO). The questions form an in-built risk assessment checklist designed to identify Undergraduate and Postgraduate Taught student projects which are judged to pose minimal risks and eligible for ‘standard’ risk review via a School Research Ethics Officer (SREO).

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| **Q1.** Does the research involve potentially vulnerable people or groups in a dependent or unequal relationship? E.g., young people under 18, people with conditions associated with social stigma including mental health concerns, people in social care settings)? | Y/N |
| **Q2.** Does the research involve individuals or groups where permission of a gatekeeper is required for initial or continued access to participants? E.g., non-NHS support groups and organisations supporting public health based in the community, traditional communities (at home and overseas), school pupils, or Medical Students? | Y/N |
| **Q3.** Does the research involve discussion of sensitive topics or collection of sensitive data about participants? E.g., health status, sexual activity, drug use, ethnicity, political behavior, potentially illegal activities. Or those where researchers may have a duty to report (such as safeguarding concerns; possible fraud; terrorism; money laundering)? | Y/N |
| **Q4.** Could the research involve more than minimal psychological stress, anxiety, or humiliation for the participant? Might the study cause harm or negative consequences beyond the risks encountered in everyday life? | Y/N |
| **Q5.** Will the study involve invasive procedures or psychological interventions outside of standard practice? | Y/N |
| **Q6.** Will the research involve deception? And/or will participants be required to take part in the study without their consent or knowledge at the time (e.g., covert observation of people in non-public places)? | Y/N |
| **Q7.** Does the research involve collecting/storing personal or sensitive participant data which cannot be anonymised? | Y/N |
| **Q8.** Will the research involve access to records of personal or confidential information, including genetic, biometric, or other biological information, concerning identifiable individuals? For example, collection of an inner-cheek swab for detection of the APOE-e4 genetic risk variant for Alzheimer’s Disease. | Y/N |
| **Q9.** Does the research involve the processing of data beyond that for which informed consent has been given? Will access to non-anonymised personal data previously taken for another purpose be utilised? | Y/N |
| **Q10.** Will data be gathered through social media channels or online groups/websites without the explicit informed consent of each individual? | Y/N |
| **Q11.** Will the research involve blood/saliva/tissue samples, MRI imaging, or other methods which involve physical risk to the participant and/or careful screening or specialist skills of the researchers in order to maintain safety? | Y/N |
| **Q12.** Is there a possibility that research activity might uncover unexpected and possibly clinically relevant findings? E.g., MRI scanning projects, projects involving taking blood samples, or cheek swabs, that may or may not have ethical consequences. | Y/N |
| **Q13.** Will your study involve staff or students of the Universities of Brighton or Sussex travelling to any country with a current Foreign Commonwealth and Development Office (FCDO) warning against travel? Will any fieldwork associated with the project be undertaken outside the UK? | Y/N |
| **Q14.** Will your study involve visiting participants in their homes, public spaces, or a similarly uncontrolled environment, unaccompanied? | Y/N |
| **» Risk Assessment** |  |
| **Q15.** Does your study pose any other ethical, safety, regulatory or reputational risk not covered above? (E.g., a risk to the safety and wellbeing of the researchers and other staff?) | Y/N |

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| **16. ALL APPLICANTS:** If you have answered Yes to ANY of the above questions, your application may be considered as HIGH risk. If, however, you wish to make a case that your application should be considered as STANDARD risk please enter the reasons here. Researchers should note that the SREO or RGEC may decide NOT to agree with the case that you have made. |

**Detailed Proposal**

**Taught Student Ethical Review Form**

**» Section 1. Methodology, Data Collection and Analysis (Please provide full details)**

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| 1.1. What is the principal research question/objective? Please clearly state the hypothesis to be tested. Please put this in language comprehensible to a lay person. |
| 1.2. What research method(s) do you plan to use; e.g. interview, questionnaire/self-completion questionnaire, field observation, audio/audio-visual recording etc.? |
| 1.3. How many people do you envisage will participate, who are they (e.g. age and gender) and how will they be selected? |
| 1.4 . Please state the rationale for the number of participants to be recruited (please note that it is unethical to recruit either more, or less, participants than required to adequately power a study). |
| 1.5. What are the inclusion/exclusion criteria? |
| 1.6. Where will the project be carried out e.g. public place, in researcher's office, in private office at an organisation? Please list all research locations to be used. |
| 1.7. How will the results be analysed and by whom? |

**» Section 2. Informed Consent and Recruitment**

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| 2.1. How will participants be approached and recruited? What specific mechanisms will be used e.g. social media, university circulation lists, intranets or any other external websites? |
| 2.2. Please describe the process you will use to ensure your participants are freely giving fully informed consent to participate. In most instances this will always include the provision of an Information Sheet and will require a Consent Form unless there is a strong justification for not doing so. (Please provide details if this is the case). |
| 2.3. Who will be receiving informed consent? What training or experience have they received to do so? |
| 2.4. Participants should have the right to withdraw from the research at any time. Participants should also be able to withdraw their data if it is linked to them and should be told when this will no longer be possible (e.g. once it has been included in the final report). Please describe the exact arrangements for withdrawal from participation and withdrawal of data for your study. |
| 2.5. Does the study involve participants who are particularly vulnerable, or unable to give informed consent, or in a dependent position (e.g. young people under 18, people with learning difficulties, over-researched groups or people in care facilities, including prisons)? Additionally, has Patient and Public Involvement (PPI) been sought? (Input from those with lived experience who can contribute their expertise, feedback and insights into writing and designing literature for study participants). |
| 2.6. Will a chaperone be required to be present during interviews? If so, please describe the chaperone arrangements. |
| 2.7. Will participants be compensated for their time or be reimbursed for expenses? If so, how much? |
| 2.8. Could the study induce psychological stress or anxiety, or produce humiliation, or cause harm or negative consequences beyond the risks encountered in normal life? |
| 2.9. If the research involves the possibility that your investigations might uncover unexpected and possibly clinically relevant findings, how will this be managed? |
| 2.10. Can you think of anything else that might be potentially harmful to participants in this research? |
| 2.11. Will you inform participants of the results of the research? Please give details of how you will inform participants or justify if not doing so. |

**» Section 3. Data Protection, Confidentiality and Records Management**

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| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | 3.1. Does the project require the collection or processing of personal data? | Yes/No |  |  |  |  | |
| 3.2. How will you ensure that the processing of personal information and personal identifiable information related to the study will be in full compliance with the Data Protection Act (2018) and the GDPR? |
| 3.3. For student research, the Supervisor is the custodian of the research data and is responsible for its management, including determining security and access rights. It is particularly important that access to personal data is strictly confined only to those granted access with prior consent. Please indicate whether any sharing of personal data will be required at any stage (i.e. within the research team) and ensure that all such details are reflected in documents or participant communications. |
| |  |  | | --- | --- | | 3.4. If you are undertaking an online survey please identify the platform you are using (ensuring it is a University approved tool, such as Qualtrics or JISC Online). |  | |
| 3.5. Please provide details of the plans to maintain and share any personal data collected, as well as safe disposal of the personal information on completion of the research process. |
| |  | | --- | | 3.6. Data storage arrangements must reflect the sensitivity of the data. Appropriate levels of storage security must therefore be established by the Supervisor and maintained by the research team. What steps will be taken by the Supervisor to take full responsibility, throughout the duration of the study, for ensuring appropriate storage and security of information (including research data, consent forms and administrative records)? | |
| 3.7. Supervisors must determine and arrange the retention of research data for appropriate periods following the conclusion of the project in line with University requirements (<http://www.sussex.ac.uk/ogs/policies/information/recordsmanagementguidance>). Please outline how any personal data will be destroyed on completion of the research process (all such details should be reflected in documents or communications for participants). Usually personal data will only be retained strictly as is necessary. |

**» Section 4. Researcher(s) Safety and Wellbeing**

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| |  |  |  | | --- | --- | --- | | 4.1. Could the nature or subject of the research potentially have an emotionally disturbing impact on the researcher(s)? | Yes / No |  | |
| 4.2. If yes, briefly describe what measures will be taken to help the researcher(s) to manage this. |
| |  |  |  | | --- | --- | --- | | 4.3. Could the nature or subject of the research potentially expose the researcher(s) to threats of physical violence and/or verbal abuse? | Yes / No |  | |
| 4.4. If yes, briefly describe what measures will be taken to mitigate this. |
| |  |  |  | | --- | --- | --- | | 4.5. Does the research involve any fieldwork? | Yes / No |  | |
| 4.6. If yes, where will the fieldwork take place? |
| |  |  |  | | --- | --- | --- | | 4.7. Will any researchers be in a lone working situation at any point? | Yes / No |  | |
| 4.8. If yes, briefly describe what measures will be taken to mitigate this. |
| 4.9. Can you think of anything else that might be potentially harmful to the researcher(s) in this research? |

**» Section 5. Other Ethical Clearances, Gatekeepers and Permissions**

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| |  |  |  | | --- | --- | --- | | 5.1. Are any other ethical clearances or gatekeeper permissions required for access to participants or the research sites? | Yes / No |  | |
| 5.2. If yes, please give further details including the name and address of the organisation. If other ethical approval has already been received please attach evidence of approval, otherwise you will need to supply it when ready. |
| 5.3. Please also consider whether there are other ethical issues you should be covering here. Please also make reference to the professional code of conduct (such as the University of Sussex’s Code of Practice for Research), you intend to follow in your research. |

**» Section 6. Conflicts of interest**

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| |  |  | | --- | --- | | 6.1. Do any researchers have any financial interests in this research or its outcomes or any relevant affiliations? | Yes / No | |
| 6.2. If yes, please give further details. |