Brightonn and Sussex Medical School logo**RGEC Application Form: Standard Risk Pathway**

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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.invo.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 ethical 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.

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| 1. Will your study involve participants who are particularly vulnerable or unable to give informed consent or in a dependent position (e.g. young people under 18, individuals with learning difficulties, or people with conditions associated with social stigma including mental health concerns, people in care facilities, including prisons, or over-researched groups)? | Y/N |
| 2. 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, mining of data from social media sources), and/or will deception of any sort be used? Will access to non-anonymised personal data previously taken for another purpose be utilised? | Y/N |
| 3. Will the study include groups where permission is normally required for access to its members, for e.g. non-NHS support groups and organisations supporting public health based in the community, traditional communities (at home and overseas), school pupils, or an overused population such as Medical Students? | Y/N |
| 4. Will it be impossible to ensure that identities or information cannot be linked back to individual participants in any way (including after anonymisation) in the final writing up of the research? | Y/N |
| 5. Might the study induce psychological stress or anxiety, or produce humiliation or cause harm or negative consequences beyond the risks encountered in the everyday life of participants? Will the study involve psychological interventions or processes outside of standard practice and will any invasive, significantly burdensome, or potentially harmful procedures or activities of any kind be undertaken? | Y/N |
| 6. Will the study involve discussion of sensitive topics (e.g. health status, sexual activity, drug use, ethnicity, political behaviour, potentially illegal activities), or those where researchers may have a duty to report (e.g. safeguarding concerns; possible fraud; terrorisms; money laundering)? | Y/N |
| 7. Will your study involve staff or students of the University of Sussex travelling to any country with a current Foreign and Commonwealth (FCO) warning against travel? | Y/N |
| 8. Will your study involve visiting participants in their home, public spaces or a similarly uncontrolled environment, unaccompanied? | Y/N |
| 9. Will your study involve the use of chemicals which could expose members of the University to carcinogens, mutagens, sensitizers, toxins, flammables/explosives, risk of asphyxiation? Or, any Chemical Weapon Precursors or Schedule 5 toxins? | Y/N |
| 10. Will your study involve the use of radioactive materials, X-rays (i.e. CT scanner or similar imaging equipment), Class 3 or 4 lasers, or strong magnetic fields? | Y/N |
| 11. Will your study involve the use of any scheduled drug/s, drug precursors or the synthesis of novel psychoactive substances? Are alcoholic drinks, drugs, placebos or other substances (such as food substances or vitamins) to be administered to the study participants? | Y/N |
| 12. Will your study involve work with: An identifiable risk of contracting a communicable disease from study participants? Biological agents in group 2, 3 or 4? Creation/use of genetically modified organisms? Storage and/or analysis of human biological tissue whether or not this will be carried out under the University of Sussex HTA license? | Y/N |
| 13. Is there a possibility that research activity might uncover unexpected and possibly clinically relevant findings? For e.g. MRI scanning projects, taking bloods, cheek swabs that may or may not have ethical consequences. | Y/N |
| 14. Does your study pose any other ethical, safety, regulatory or reputational risk not covered above? | Y/N |

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| 15. TAUGHT STUDENTS ONLY  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**

**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 access to personal records? | 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 General Data Protection Regulation (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? | 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. |