Brighton and Sussex Medical School logo

**RGEC Application Form:**

**Advanced Research Ethical Review Form for Staff & PGR Applicants**

Please note that this form is intended only to be used to complete a draft application, for reference and training purposes. All applications to RGEC should be made via the online [**ethics application system in Sussex Direct**](https://direct.sussex.ac.uk/page.php?realm=research&page=ethical_review_list)

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| **» BSMS Ethical Review Checklist** |  |
| 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)? | Yes/No |
| 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? | Yes/No |
| 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)? | Yes/No |
| 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? | Yes/No |
| Q5. Will the study involve invasive procedures or psychological interventions outside of standard practice? | Yes/No |
| 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)? | Yes/No |
| Q7. Does the research involve collecting/storing personal or sensitive participant data which cannot be anonymised? | Yes/No |
| 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. | Yes/No |
| 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? | Yes/No |
| Q10. Will data be gathered through social media channels or online groups/websites without the explicit informed consent of each individual? | Yes/No |
| 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? | Yes/No |
| 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. | Yes/No |
| 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? | Yes/No |
| Q14.Will your study involve visiting participants in their homes, public spaces, or a similarly uncontrolled environment, unaccompanied? | Yes/No |
| **» 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?) | Yes/No |
| Q16. 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. |  |
| |  | | --- | | **» Section 1. Methodology, Data Collection and Analysis (Please provide full details)** | | * 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. What research method(s) do you plan to use; e.g. interview, questionnaire/self-completion questionnaire, field observation, audio/audio-visual recording? | | * 1. How many people do you envisage will participate, who are they (e.g. age and gender) and how will they be selected? | | * 1. Please state the rationale for the number of participants to be recruited (please note that it is unethical to recruit either more, or fewer, participants than required to adequately power a study). | | * 1. What are the inclusion/exclusion criteria? | | * 1. 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. How will the results be analysed and by whom? | | **» Section 2. Informed Consent and Recruitment** | | 2.1. How will participants be approached and recruited? What specific channels will be used e.g. hard copy adverts, internal email circulation lists, external websites, participant survey sites, professional networks, electronic communities such as online forums, private message boards, or closed discussion groups, social media, organisational gatekeepers, word of mouth discussions. | | 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. (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 social care facilities)? | | 2.6. If vulnerable participants will be recruited, then Patient and Public Involvement (PPI) should be sought from those with lived experience who can contribute their expertise, feedback and insights into writing and designing participant facing literature. Has this occurred? | | |  |  | | --- | --- | | 2.7. Will a chaperone be required to be present during interviews? If so, please describe the chaperone arrangements. |  | | | 2.8. Is Disclosure and Barring Service (DBS) clearance necessary for this project? (Please provide details if this is the case). | | 2.9. Will participants be asked to take part in the study without their consent or knowledge at the time (e.g. covert observation of people), or will deception of any sort be involved? Please refer to the British Psychological Society Code of Ethics and Conduct for further information. | | 2.10. Will participants be compensated for their time or be reimbursed for expenses? If Yes, explain how compensation will occur (money, voucher, participation credit) and how much. | | 2.11. Could the study induce psychological stress or anxiety, or produce humiliation, or cause harm or negative consequences beyond the risks encountered in normal life? If Yes, explain how this will be mitigated? | | 2.12. Are alcoholic drinks, drugs, placebos or other substances (such as food substances or vitamins) to be administered to the study participants? If Yes, please set out how you will actively monitor the wellbeing and safety of participants while substances are in their system. | | 2.13. If the research involves physical intervention (e.g. imaging), have you considered the possibility that your investigations might uncover unexpected and possibly clinically relevant findings? How will this be managed? | | 2.14. Can you think of anything else that might be potentially harmful to participants in this research? | | 2.15. 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** | | |  |  |  | | --- | --- | --- | | 3.1. Will you be processing (i.e. collecting, recording, storing, or otherwise using) personal data as part of this project? (Personal data is any information relating to an identified or identifiable living person).  If Yes, please provide details of the personal data to be collected. |  |  | | | 3.2. If Yes, which organisation(s) will act as Data Controller (i.e. the organisation which determines the purposes and means of processing the data) for personal data collected and used as part of the project? | | 3.3. Will you be processing (i.e. collecting, recording, storing, or otherwise using) 'SPECIAL CATEGORY' personal data? | | |  |  | | --- | --- | | 3.4. Describe what measures will be put in place to ensure confidentiality of personal data, where appropriate. |  | | | 3.5. In general terms, who will have access to the data generated at each stage of the research, and in what form (e.g. identifiable, pseudonymised, anonymised)? | | 3.6. What steps will be taken to ensure the security of data processed during the project, including any identifiable personal data, other than those already described earlier in this form? | | 3.7. Will any online questionnaires be completed anonymously? If Yes, please explain how anonymisation of participants will be ensured? | | 3.8. Will research data only be identifiable by a unique identifier (e.g. code/pseudonym)? If Yes, please explain how this will be attributed. | | 3.9. Will lists of identity numbers or pseudonyms linked to names and/or addresses be stored securely and separately from the research data? If Yes, explain how this will occur. | | 3.10. Will all place names and institutions which could lead to the identification of individuals or organisations be changed unless this is consented to explicitly in the consent form? | | 3.11. Will all identifiable personal data be destroyed within a defined period after the project has ended? Please outline when this will take place (this should take into account regulatory and funder requirements. It does not need to be a specific date, but should indicate an appropriate timeframe e.g., 3 years after publication). | | 3.12. Will all personal data gathered be treated in strict confidence and never disclosed to any third parties or service providers? | | **» Section 4. Researcher(s) Safety and Wellbeing** | | |  |  | | --- | --- | | 4.1. Does the project involve working with any substances and/or equipment which may be considered hazardous? (Please refer to the University's Control of Hazardous Substances Policy). |  | | | 4.2. If yes, briefly state the substance(s) or equipment and briefly describe measures you will take to ensure the researchers safety and wellbeing. | | |  |  | | --- | --- | | 4.3. Could the nature or subject of the research potentially have an emotionally disturbing impact on the researcher(s)? |  | | | 4.4. I If yes, briefly describe what measures will be taken to help the researcher(s) to manage this. | | |  |  | | --- | --- | | 4.5. Could the nature or subject of the research potentially expose the researcher(s) to threats of physical violence and/or verbal abuse? |  | | | 4.6. If yes, briefly describe what measures will be taken to mitigate this. | | |  |  | | --- | --- | | 4.7. Does the research involve any fieldwork - Overseas or in the UK? |  | | | 4.8. If yes, where will the fieldwork take place? If the fieldwork will take place overseas, please ensure that the relevant Risk Assessment form has been completed and the relevant University Insurance Manager has been consulted. Please append a copy of the Risk Assessment form to your application. | | |  |  | | --- | --- | | 4.9. Will any researchers be in a lone working situation? |  | | | 4.10. If Yes, please describe the procedures to be put in place to protect the researcher's safety as far as possible. | | 4.11. 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** | | |  |  | | --- | --- | | 5.1. Are any other ethics clearances or gatekeeper permissions required for the project to access participants or research sites? E.g. local ethics approval from the host country (or countries) where research outside the UK will be carried out, or Gatekeeper approval to access certain participant populations. |  | | | 5.2. If yes, please give further details including the name and address of the organisation. If other ethics approval has already been received, please attach evidence of approval, otherwise you will need to supply it when ready. | | 5.3. If the research involves storing and/or analysing human tissue or any human material will this be carried out under the University's HTA license? | | 5.4. 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** | | 6.1. Do any researchers have any financial interests in this research or its outcomes or any relevant affiliations? | | 6.2. If yes, please give further details. | | |