

Section 4: Application for Ethical Approval

Who should complete this form?

The Cambridge Psychology Research Ethics Committee considers applications for ethical approval for research programmes in human psychology. Studies involving patients attending NHS clinics or administration of controlled or prescription pharmaceuticals or devices would normally seek ethical approval via the Health Research Authority. If you would like further advice on the suitability of a project for review, use the contact addresses given below.

How is the form completed?

Answer all questions using the notes and Handbook as guidance. Keep all responses to questions within the boxes. There is no limit to the length of responses; the boxes will expand to accommodate the text. However, be brief but precise. Clarity is important to effective and timely ethical review.

Any supporting information (e.g. questionnaires, advertising materials, Information Sheets, Consent Forms) should be clearly labelled as appendices to the application form and referred to as appropriate in responses to questions.

The primary applicant or any of the co-applicants can complete the form, although the Corresponding Applicant will be the first point-of-contact for communication between the Committee and the study team.

The Committee assumes that any application relating to a study that forms part of a taught course has been discussed with the Head of Department. Copies of all correspondence from the Committee relating to such applications will also be sent to the Head of Department.

All applicants must sign and date the form. Electronic signatures or scanned images of signatures are acceptable. Ink signed signatures should be scanned and submitted with the application form.

Once complete where is the form submitted?

Completed application forms and appendices can be emailed to: SBSEthics@admin.cam.ac.uk or sent on digital media (e.g. CD, DVD) to: The Secretary of the Cambridge Psychology Research Ethics Committee, School of the Biological Sciences, University of Cambridge, 17 Mill Lane, Cambridge CB2 1RX.

If you have any queries regarding submission contact: SBSEthics@admin.cam.ac.uk.

What happens next?

Refer to the web-site of the Cambridge Psychology Research Ethics Committee ([Cambridge Psychology Research Ethics Committee | School of the Biological Sciences](#)) for information on the review process and time-lines for ethical approval.



UNIVERSITY OF CAMBRIDGE

COUNCIL OF THE SCHOOL OF THE BIOLOGICAL SCIENCES
Cambridge Psychology Research Ethics Committee

Question 1: Title of the study

Notes: The title should be a single sentence

Question 2: Primary applicant

Notes: The primary applicant is the name of the person who has overall responsibility for the study. Include their appointment or position held and their qualifications. Primary applicants cannot be research students or junior research assistants. For studies where students and/or research assistants will undertake the research, the primary applicant would normally be their supervisor.

Question 3: Co-applicants

Notes: List the names of all researchers involved in the study. Include their appointment or position held and their qualifications

Question 4: Corresponding applicant

Notes: Give the name of the person to whom correspondence regarding this application is to be addressed. This person should be the primary applicant or one of the co-applicants. An email address for correspondence must be provided.

Question 5: In which Department(s) or Research Unit(s) will the study take place?

Notes: Indicate where the study procedures will take place as well as the location for the storage and analysis of data. If the study will use National Health Service facilities, give a contact name and address of the Trust R&D office.

Question 6: What are the start and end dates of the study?

Notes: If exact dates are unavailable, explain why and give approximate dates. The study should be no more than 5 years in duration. Longer studies will need to submit for ethical review every 5 years.

Question 7: Briefly describe the purpose and rationale of the research

Notes: Attach any detailed research proposals, if they have been submitted or will be submitted to a funding body. Make the objectives of the study clear.

Question 8: Who is funding the costs of the study?

Notes: Give the name and address of funding bodies or other sponsorship (other than the University of Cambridge) involved in providing resources for the study.

Question 9: Describe the methods and procedures of the study

Notes: Attach any relevant material (questionnaires, supporting information etc.) as appendices and summarise them briefly here (e.g. Cognitive Failures Questionnaire: a standardised self-report measure on the frequency of everyday cognitive slips). Do not merely list the names of measures and/or their acronyms. Include information about any interventions, interview schedules, duration, order and frequency of assessments. It should be clear exactly what will happen to participants. If you are collecting any human tissue samples (for example, saliva, urine, blood, breast milk), please confirm that they will be stored at a location that has an appropriate licence from the Human Tissue Authority. If relevant, indicate the types of personal data that will be recorded and confirm its collection is necessary and proportionate to the aims of the study.

Question 9a: Does the study involve any pharmaceutical or other compounds with physiological effects?

Notes: This includes all compounds licensed under the Medicines Act. However, some compounds may be considered as Investigational Medical Products and studies of them, therefore, as clinical trials (CTIMPs). If there is any ambiguity, investigators should contact the Medicines and Healthcare Products Regulatory Agency (MHRA) for guidance. Include any response from the MHRA in your application. CTIMPs must seek NRES approval.

If “yes”, complete Appendix A

Question 10: What ethical issues does this study raise and what measures have been taken to address them?

Notes: Describe any discomfort or inconvenience that participants may experience. Include information about procedures that for some people could be physically stressful or might impinge on the safety of participants, e.g. noise levels, visual stimuli, equipment; or that for some people could be psychologically stressful, e.g. mood induction procedures, tasks with high failure rate. Indicate what procedures are in place if clinically relevant information arises from the study (e.g. from brain scans or questionnaire responses that might indicate that a participant is at risk). Describe risks associated with any personal data that is collected.

Question 11: Who will the participants be?

Notes: Describe the groups of participants that will be recruited and the principal eligibility criteria and ineligibility criteria. Make clear how many participants you plan to recruit into the study in total.

Question 12: Describe the recruitment procedures for the study

Notes: Gives details of how potential participants will be identified or recruited. Include all advertising materials (posters, emails, letters etc.) as appendices and refer to them as appropriate. Describe any screening examinations. If it serves to explain the procedures better, include as an appendix a flow chart and refer to it.

Question 13: Describe the procedures to obtain informed consent

*Notes: Describe when consent will be obtained. If consent is from **adult participants**, give details of who will take consent and how it will be done. If you plan to seek informed consent from **vulnerable groups** (e.g. people with learning difficulties, victims of crime), say how you will ensure that consent is voluntary and fully informed.*

*If you are recruiting **children or young adults** (aged under 18 years) specify the age-range of participants and describe the arrangements for seeking informed consent from a person with parental responsibility. If you intend to provide children under 16 with information about the study and seek agreement, outline how this process will vary according to their age and level of understanding.*

How long will you allow potential participants to decide whether or not to take part? What arrangements have been made for people who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?

If you are not obtaining consent, explain why not.

Question 14: Will consent be written?

Yes/No (delete as appropriate)

*Notes: If **yes**, include a consent form as an appendix. If **no**, describe and justify an alternative procedure (verbal, electronic etc.) in the space below.*

Guidance on how to draft Participant Information sheet and Consent form can be found on the Psychology Research Ethics Committee website.

Question 15: What will participants be told about the study? Will any information on procedures or the purpose of study be withheld?

Notes: Include an Information Sheet that sets out the purpose of the study and what will be required of the participant as appendices and refer to it as appropriate. If any information is to be withheld, justify this decision. More than one Information Sheet may be necessary.

Question 16: Does the data collected in this study pose a very high risk? Will personally identifiable information be made available beyond the research team?

*Notes: Studies collecting **high-risk** data should seek advice from the University's Data Protection Officer. High-risk data includes personal data that, if there were a breach, could be extremely harmful to an individual's health, safety, professional or personal life; the profiling of children or vulnerable individuals; direct collection of data without consent; combining or processing data in a way that could have significant effects for individuals.*

If personal data is being transferred outside of the research team (for example, for secondary use) indicate to whom and describe how consent will be obtained.

Question 17: What payments, expenses or other benefits and inducements will participants receive?

Notes: Give details. If it is monetary say how much, how it will be paid and on what basis is the amount determined.

Question 18: At the end of the study, what will participants be told about the investigation?

Notes: Give details of debriefings, ways of alleviating any distress that might be caused by the study and ways of dealing with any clinical problem that may arise relating to the focus of the study.

Question 19: Has the person carrying out the study had previous experience of the procedures? If not, who will supervise that person?

Notes: Say who will be undertaking the procedures involved and what training and/or experience they have. If supervision is necessary, indicate who will provide it.

Question 20: What arrangements are there for insurance and/or indemnity to meet the potential legal liability for harm to participants arising from the conduct of the study?

Notes: Insurance would normally be provided by the University's or Medical Research Council's insurance for persons employed by them or working in their institutions. Please contact the appropriate Insurance Office to arrange for insurance. If you do not have an appropriate institutional affiliation, say how you will provide public indemnity insurance, including insurance against non-negligent injury to participants. Evidence of insurance is required before a Letter of Approval can be issued.

Question 21: What arrangements are there for data security during and after the study?

*Notes: Digital data stored on a computer requires compliance with the General Data Protection Regulation; indicate if you have discussed this with your Departmental Data Protection Officer and describe any special circumstances that have been identified from that discussion. **Confirm that all applicants have received GDPR training.** Say who will have access to participants' personal data during the study and for how long personal data will be stored or accessed after the study has ended, **and whether data will be transferred or stored outside the UK.***

Signatures of the study team (including date)

Notes: The primary applicant and all co-applicants must sign and date the form. Scanned signatures are acceptable.

The Principal Investigator and anyone on the research team with direct contact with participants during the administration of the active compounds should have a current certificate of Good Clinical Practice (GCP). Please include the certificates with the application.

Appendix A: Additional information for studies involving the administration of pharmaceuticals or compounds with physiological effects. Include the study protocol with the application.

Question A1: Specify the compound(s) to be used in the study

Notes: Include the trade name, marketing authorisation product licence holder, its form (for example, capsules, liquid) and concentration, any modifications (for example, over-encapsulation), and any other relevant details. If more than one compound is to be used, give details for each separately.

Question A2: How will the compound(s) be used in the study?

Notes: Give details of the intended dose, the maximum dose, the frequency of administration, and route of administration.

Question A3: What are the known side-effects and interactions with other compounds?

Notes: List each of the known side-effects and the corresponding risk of encountering them. Are there any known side-effects with commonly prescribed products, over-the-counter products, foods, and so on?

Question A4: What will participants be told about the compound(s)?

Notes: Describe what and how participants will be told about the risks of the compound.

Question A5: What procedures are in place to mitigate the risks?

Notes: Give details of what emergency procedures are in place. Confirm that a medical qualified person is available when the compound is administered. Will there be an antidote available, and who will administer it? What procedures are in place for follow-up care? If the compound is blinded, how can the blind be broken if necessary?