GUIDANCE NOTES FOR COMPLETING YOUR APPLICATION TO THE SCIENCES & TECHNOLOGY CROSS-SCHOOLS RESEARCH ETHICS COMMITTEE

Recent updates are flagged in red.

Within the ethics application system in Sussex Direct, the "help" buttons for each section contain quite a lot of information on how to complete your form. Many applications are returned to applicants before they can be sent to CREC members for review because they are incomplete and/or unclear. Common problems (and solutions) are noted below.

A project only needs to be reviewed by the CREC once.

- If you already have CREC (or NHS, etc.) approval for a "high risk" study, then you need to apply for an amendment in which you will name the students and provide updated material. This amendment should be approved swiftly by Chair's action. Students may then apply to the School Research Ethics Officer (SREO) for approval, making a case for expedited review as a "low risk" project as long as they explain the prior approval and attach evidence of this (as well as all the recruitment, information, consent and debrief material).

- If two (or more) students are working on the same project, then only one application needs to be submitted to the CREC, preferably by the supervisor. However, for course requirements all students will need to complete an ethics application. A student, or preferably, the supervisor can submit the "formal" high-risk application, naming all the students that will work on the project and when approval has been obtained the other students working on the project may apply to the SREO, making a case for expedited review as a "low risk" project as long as they explain the prior approval and attach evidence of this (as well as all the recruitment, information, consent and debrief material).

PROJECT DESCRIPTION

The CREC includes people with a broad range of backgrounds – not all are scientists, and fewer are psychologists. Please ensure that your project description is as clear and jargon-free as possible. Do not simply copy-and-paste from a grant application. There is no need to include references. The key task here is to justify why you intend to do what you intend to do with/to human participants – any ethical issues should be flagged here

SECTION A

If your project IS "high risk", then leave the final item in Section A blank. Otherwise, the form will switch to the "low risk" version (part 1 and part B), the CREC chair will have to return your form, and you will have to complete the correct "high risk" version (part 1 and part B).

SECTIONs B and C

If you intend to do any off-campus work, then you will need to explain how the safety of participants and researchers will be ensured. If you are doing data collection in public spaces, then you may wish to contact the insurance office for advice: [insurance@sussex.ac.uk]

When a researcher is working off-campus, you will need to explain procedures to ensure their safety. This is often done by ensuring that another member of the research team has a record of the time and location of off-campus work. You should also describe ay check-in procedure to be used (e.g., a phone call or text message saying "I have now finished the interview, and I am heading back to work"), and what will be done if no check-in message is received.

If your study involves auditory stimuli, then you should clarify that the frequency, volume, and duration of exposures are safe.

Include information about any participant payment/reimbursement. Reimbursement rates should normally be around £7 per hour. Rates in excess of this must be justified.

Prizes in **prize draws** should normally be no more than £50. Greater prizes must be justified (beyond simply trying to get more people in). If you want to retain people in a longitudinal study, then you may want clarify at the start that only people who complete the follow-up will be able to enter the prize draw.

In gambling studies, all participants must be paid the same amount. This should reflect the time given over to participation. It is acceptable to lead people to believe that payment will reflect task performance, but you will then need to explain in a debrief that all participants receive the same amount, and then ask people whether they still give their consent for you to use their data, or whether they would prefer to withdraw their consent. The minor deception should be flagged in Section A, but it can be justified at the end of Section A.

If you are transcribing recordings of interviews or testing sessions, then you must clarify who will do the transcription. If transcription is to be done by someone other than the researchers, then they should be asked to sign a confidentiality agreement.

Specify where data will be stored on campus (e.g., in a locked filing cabinet in an office at University of Sussex; in password-protected files on a University server). Personal data should not be stored in private premises or on personal computers. C25: data files should be stored as password protected, or encrypted, rather than being stored on a computer that is overall password protected but without further specific protection for the study data.

Specify for how long all forms of data will be kept. Anonymised data can normally be kept for up to 10 years. Personal details may not need to be kept for this long - especially if there is a date beyond which withdrawal of data is not possible.

SECTION C

If your study requires participants to eat or drink, then you must clarify the source of the food/drink and its safety. Information about allergies must clearly conveyed in information sheets, and participants should be asked to confirm on the consent form that no allergy-related exclusion criteria apply to them.

If your study involves any activities (brain stimulation, flashing lights, etc.) that have any chance of provoking seizures, then this risk and must be explained to potential participants. So too should the implications of a seizure for driving licence validity.

If you are recruiting children for data collection in schools, then you should refer to:
SOP for obtaining consent for research with child participants in schools [PDF 189.69KB]
available on this page: http://www.sussex.ac.uk/staff/research/governance/apply

Describe where data collection will take place, and be specific. For example, if data collection is to be carried out in schools, then you will need to specify whether this will be in a classroom or another room, whether the researchers will be alone with children at any time, and whether others will be able to see this interaction. If one-to-one testing is to be carried out in a separate room, then the door to the room should be left ajar.

There is no need to attach CRC/DBS clearance certificates

ATTACHMENTS

Include all materials to be presented to (potential) participants: recruitment materials, information sheets, consent forms, questionnaires, etc. If you are using visual stimuli presented on a screen, then you should provide copies of a representative selection on images.

If your study involves obtaining verbal assent from child participants, you must upload a script of the text that will be read to them.

If you are using visual stimuli presented on a screen, then you should provide copies of a representative selection of images. If you are presenting videos, then you must provide an outline of the "plot" and include representative images. It is not sufficient to provide a link to an online video, as CREC members work with PDF versions of applications.

INFORMATION SHEETS and CONSENT FORMS

Template information sheets and consent forms are available here: [www.sussex.ac.uk/staff/research/governance/apply]

Julia Simner has recently produced a combined, shorter and much improved version of these forms which can be downloaded from the School's ethics webpages:

[www.sussex.ac.uk/psychology/internal/documents/infoconsent-template-revised.doc].

If you use these forms please make sure that you print two copies of this form (one for the participant and one for you).

They do not HAVE to be used, but they do contain everything you might be expected to include in these documents.

Information sheets should include descriptions of a representative selection of items to be presented to participants (e.g., give a clear indication of the most intrusive or confronting items).

Ensure that you give the correct CREC name, email address, and project reference on these documents: ""This study has been approved by the Sciences & Technology Cross-Schools Research Ethics Committee (crecscitec@sussex.ac.uk). The project reference number is ER/XXXXX"

Do not include personal email addresses on information sheets and consent forms - use your university email address

The information sheet should include the following statement: "The University of Sussex has insurance in place to cover its legal liabilities in respect of this study"

If you have any exclusion criteria, then these must be clearly stated on the information sheet, and the consent form should include a tick box that participants can use to confirm that the exclusion criteria do not apply to them.

If you intend to use verbal consent procedures, then you must include a copy of the "script" to be used to explain the study, and you must clearly explain how you will record consent.

Ask a person not directly involved in the study (preferably not an academic) to read over your information sheet and consent form to ensure that they are easy to understand and free of technical jargon.

Before submitting your form, click on the "create merged PDF" version and check that all text/images in all of your attachments can be seen. Documents prepared in "landscape" page layout may be truncated, unless you rotate them before saving as a PDF to upload.

Please ensure that the merged PDF does not exceed 5MB.

! SUPERVISORS !

After clicking "approve", you must also press the button to forward the application to the Sciences + Technology CREC. If you do not, the application will sit in your folder, but your student will think that it is under review.

AMENDMENTS + EXTENSIONS

All amendments to procedures or materials should be notified to the CREC. To do so:
1] open the original application, and click on "copy"
2] change the title "AMENDMENT TO ER/... [insert title]"
3] ensure that the project description clearly outlines the proposed changes (you can delete the rest of the project description)
4] ensure that all new or amended materials are attached.

If you require an extension to the approval period:
1] open the original application, and click on "copy"
2] change the title "EXTENSION OF ER/... [insert title]"
3] change the project end date
4] in the project description state that all materials and methods have been used without incident and no changes to these will be made.

HTA

For all C-REC applications that involve HTA-regulated procedures (that is, **anything involving taking bloods, saliva, urine or any other samples which contain cells**), the applicants should incorporate into their applications the Standard Operating Procedures for collection of samples, risk assessment, and informed consent. This includes a SEPARATE consent form for the samples, which is compliant with the HTA regulations – these forms can all be seen on the HTA website:

http://www.sussex.ac.uk/lifesci/internal/servicesandsupport/ethics/humantissue

Applicants need to complete an HTA training session with Majid Hafezparast (Life Sciences), Nadia Lovegrove/Lisa Woodbine/Heather Fawcett (Genome), Jenny Rusted (Psychology). This is a requirement before sample collection begins.

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Updated by David Reby
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