Guidance on reviewing CUREC 1A applications

This guide has been written to help Departmental Research Ethics Committees (DRECs) to consider applications for ethical review made using the CUREC 1A checklist. However, many sections of this guidance will also be useful for researchers preparing an application. An application consists of the completed and signed CUREC 1A checklist, plus relevant supporting documents, such as information sheets and consent forms.

The sections which follow describe how to interpret and review the checklist itself, plus supporting information.

The CUREC 1A checklist [1] is the application form for social scientists and humanities researchers who want to conduct research with straightforward ethical issues. The checklist has been designed with social science methodologies in mind.[2] The CUREC 1A checklist consists of five sections. Advice on the function of each section and ways of reviewing each section follows:

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[1] CUREC's webpage on the SSH IDREC and DREC application process

[2] If researchers will involve the NHS in their research (eg equipment, facilities, staff, data), and/ or use health-related research procedures, please direct them to CUREC's webpage on how and where to apply for ethical review for more advice. They may need to apply to an NHS Research Ethics Committee instead of CUREC or obtain NHS approval for the research.

Section A: Filter for CUREC 2 applications (questions A1 – A5)

This section has two functions:

Firstly, it will direct applicants to complete a CUREC 2 form if their research raises complex ethical issues. If they need to complete a CUREC 2 form, please do not process their CUREC 1A application but ask them to fill out a CUREC 2 instead, which will need to be sent to the DREC for initial review. Once the CUREC 2 application has been reviewed and approved by the DREC, the DREC administrator will need to send it to the Social Sciences and Humanities Interdivisional Research Ethics Committee (SSH IDREC) Secretariat (via their email address) **within three weeks of receipt**, ensuring that sufficient time is left for the SSH IDREC to perform a final review.

Secondly, the Section A filter in the CUREC 1A application helps research with borderline complex issues to stay within the CUREC 1A application process if researchers are able to conduct the research using CUREC's "Approved Procedures". (For more information about the function of Approved Procedures and the types of research they cover please see CUREC's webpage on Approved Procedures.) If this is the case, they must provide the number of the relevant Approved Procedure in this section and the Approved Procedure has to be applied to all of the research.

Section B: Project details and description

Contact details (questions B1 – B7)

The Principal Researcher is either the supervisor (in the case of student research) or the Principal Investigator (PI) (in the case of staff research). A student may still write the CUREC 1A application and correspond with the committee, in consultation with their supervisor. Applicants should state the name of their Department or Faculty, not their College. Applicants must also correspond using their University 'ox.ac.uk' email address (not their personal email address), and provide this email address on their application form.

Risk assessments (question B10)

Risk assessments are required for fieldwork taking place in the UK or abroad. Risk assessments may also be needed for other activities, including a COVID-19 risk assessment for research involving in person research. Please see the Safety Office's webpage on COVID-19 for further information.

All researchers undertaking research projects outside the UK will need to complete and submit a travel risk assessment to their department well in advance of their project start date in order to be covered by University travel insurance. The departmental administrator or Divisional Safety Officer will be able to give the applicant further advice on this. In relation to the ethics process, it is good practice to ask for a copy of this risk assessment form - even if it hasn't been approved by the department yet - in case there are any aspects which are relevant to the ethics review. However, it is not the role of the DREC (or the IDREC) to review the detail of risk assessments.

Dates (questions B11 and B12a)

The project duration is used to check that the project will not exceed the maximum duration of approval (which is 5 years).[3]

Initially, the applicant is asked for the duration of the whole project, as it is often the case that the element of the research involving human participants is only a small part of the overall project. This is why the applicant is then asked to specify the anticipated dates of engagement with human participants. If these latter dates are in the past, please check whether the application is retrospective (i.e. whether the engagement with human participants has already started or finished, as opposed to their course/ project as a whole).

Please note that ethical approval can only be granted to applications that have been submitted before the fieldwork has started and DRECs cannot provide approval of research that has already taken place. It is not possible to grant ethics approval retrospectively, retrospective applications should be referred to the SSH IDREC along with a letter from the Head of Department.

Dual ethics review (question B12b)

If the research is to be conducted abroad researchers either need to provide evidence of local ethics approval or explain why this is not possible/ appropriate. Further information about the purpose of this question and situations where exceptions can be made is available in Best Practice Guidance16: Ethical review of social science based research overseas.

Lay description of research (B14a)

Applicants should

a) refer to professional guidelines wherever possible (see also Section D in the CUREC 1A form) and
b) supply relevant supporting documents.

Firstly, applicants must give a brief overview of their project aims and what they will be asking participants to do. This should be in lay language. Long scientific methods descriptions are not encouraged, as the purpose of the form is primarily to review the ethical issues raised by the research.

Participant recruitment and informed consent (question B14b)

Next, applicants should describe the type of participant they plan to recruit (inclusion/ exclusion criteria) and provide information about how potential participants will be identified and approached. Any involvement of vulnerable participants must be justified. Any recruitment material (such as posters or email invitations) should also be submitted for review alongside the CUREC 1A form. The recruitment material should provide basic information about the project and what would be involved for the participants. Please see CUREC's webpage on informed consent for templates and further guidance.

Applicants should then explain the process for obtaining the participants' **informed** consent. It is important that the participants are provided with enough information to make an informed decision about whether they want to participate in the research. The process should be proportionate to the

[3] Per project, the approval given is for the project duration proposed in the CUREC application (calculated as the time between project start and end date in the project application). This duration begins on the date of the ethics approval letter. **A maximum of five years' duration of ethical approval can be applied for.** Should researchers wish to submit project amendments (see FAQs Section E) which extend this **5** year duration, they should notify the IDREC of this as part of the overall amendment notification, giving a brief summary of the research's findings so far and justifying their reasons for extension.

risks involved. The participant information sheet should include the researcher's contact details so that participants are able to contact them with questions or if they want to withdraw. These should be University of Oxford contact details not personal ones. For student projects the student's supervisor's contact details should be provided as well.

If consent is to be obtained orally rather than in writing this should be justified and the applicant should explain how they will keep an auditable record of the consent.

There are informed consent templates, including standard wording to cover a range of research contexts, available on CUREC's webpage on informed consent (examples include templates for a written and an oral consent process). Material for the participants should include enough relevant material so that they are able to make an informed decision about participating. Guidance on writing for participants is available at under our research ethics FAQ C9. Make sure the applicants have included all the relevant details (refer to the suggested headings on the templates if unsure), that the documents are written in an appropriate style for the intended audience and that they are not excessively long. The participant-facing material must make it very clear that participation is optional – it sounds obvious but this is something that is often overlooked.

For online surveys participants' informed consent can be implied by their completion and submission of the survey. Researchers do however need to provide a few paragraphs introducing the survey to make sure the participants have the information they need in order to make an informed decision. Researchers may adapt the combined informed consent process template in Appendix A of our Best Practice Guidance for Internet-Based Research.

Specific consent (question B15)

In exceptionally rare cases, it is permissible not to capture prospective consent, but only if the research aims make it impossible to capture consent beforehand. An example could be research which captures opinions in an emergency setting e.g. a frontline refugee centre, though it would still seem possible to deploy some sort of (truncated) consent process before seeking out opinions. Researchers employing deception (i.e. who are deliberately misleading participants about the nature of the research) should first check if they can apply CUREC Approved Procedure 07 (Deception of Adult Participants). If they can't fully apply this procedure, the researcher will need to complete a CUREC 2 application form.

Ethical issues (question B16)

Applicants must have received sufficient training in research integrity or research ethics, and have consulted professional guidelines as appropriate to their research area, such that they can identify the ethical issues related to their project and how these will be addressed. Please see our training webpage for further information about research integrity and ethics training options. Please also see our list of links to professional guidelines.

This section, if filled appropriately, can be a useful "jumping off" point for the applicant and committee to consider the ethical issues involved. It is appropriate for applicants to say that issues will be resolved by the informed consent process. However, this then means that the process has to be robust and cover all the sections listed in CUREC guidance. Please see CUREC's webpage on informed consent for more details.

Remember to consider the welfare of the researchers and other people involved in the research (such as interpreters) as well the welfare of the research participants. If there is a possibility that the

research could cause distress or be traumatic for the researcher(s), please refer to the Social Sciences Division's guidance on vicarious trauma.

Research involving sensitive issues (question B17)

Applicants are asked to provide details of any questions which might ask about special category data or questions that could be upsetting or embarrassing for the participants. Special Category data is data that relates to race or ethnic origin, political opinions, religious beliefs, trade union membership, genetic data, biomedical data, physical/ mental health, trade union membership, sex life or sexual orientation.

The answer should explain why the questions are necessary and have thought through what reasonable steps to take to reduce the risk of harm to the participants or themselves. For example, in an interview they could make sure the participants are aware of the nature of the questions beforehand, explain that they do not have to answer any questions they do not want to and that the interview can stop at any time, either for a break or altogether. For questionnaires it may be appropriate to provide information about relevant sources of support.

Research data management (question B18)

The next question is about responsible and secure handling of personal data. All departments/ schools/ faculties should have measures to implement the University's Data Protection and IT Security Policies. Applicants are therefore encouraged to seek out local IT contacts who can advise on the best way for them to collect, transfer and store research data, especially personal or sensitive data. They should describe their arrangements here. Advice can also be sought from the Research Data Oxford team. Please note that, according to the Oxford University Policy on the management of research data and records, "the minimum retention period for research data and records is **three years after publication** or public release of the work of the research." Research data and records are "defined as the recorded information (regardless of the form or the media in which they may exist) necessary to support or validate a research project's observations, findings or outputs." For further information please see the University's Research Data Support website. At the same time researchers should comply with the Data Protection Act guidance from the University's Legal Services office.

It is important that participants understand how identifiable they will be from the research data and any research outputs. Applicants must then reflect more closely on whether they will collect what the UK Data Protection Act (2018) defines as special category data. There is a legal requirement to obtain explicit consent for such data collection, and participants should be advised to add this to their consent processes. Bear in mind that if the researcher's processing of personal data is **likely to result in a high risk** to individuals participating in the research, they may need to complete a separate Data Protection Impact Assessment (DPIA). See the Information Compliance Team's further guidance. DRECs should be careful to pursue the reasons given by applicants who answer "No" here or don't answer the question adequately, taking advice from the IDREC and the Compliance Team as needed.

CUREC's Best Practice Guidance 09 on data collection, protection and management provides more detailed guidance.

Section C: Methods and procedures (questions C1 – C17)

This is a list of research methods and procedures. By ticking as many as apply, applicants can tell you more about what they are doing in their research, from which you can draw ethical implications. For example:

- If they only tick "analysis of existing records", they may not need CUREC approval, if those records are already publicly available.
- Snowball sampling helps understand how recruitment will operate, and could in some cases raise issues of inducement, eg if one family member recruits another to a research studying inherited health conditions.
- CUREC has best practice guidance on the use of casual or local workers.
- Covert observation, in contrast to participant observation, has implications for consent and privacy. See our best practice guidance.
- Similarly completion of questionnaires in hard copy versus online questionnaires raises different issues with regard to consent (see our Best Practice Guidance pages again for best practice about consent in internet-based research, including a combined informed consent template for online surveys). See.
- Confidentiality in a focus group will need careful explanation to research participants, including the limitations of being in a group setting on confidentiality.
- The capturing of visual data (video recording or photography) should always be justified if this is not obvious from the study design. For example, applicants should explain why photos are needed in a study whose primary outcome measure is coded interview data. Similarly, a study using an iPhone to record video of subjects being interviewed should justify why video rather than aural data is needed, eg because facial expressions need to be correlated with a subject's manner of verbal expression.
- It is important that specific consent is gained from participants (or their guardians) for any audio recording, video recording or photography of and/ or by the participant.

Cross-reference information elsewhere in the application form to make sure that the applicants have provided consistent information about the proposed research methods. If a project involves interviews and a focus group, for example, there should be an explanation of how participants will be identified and recruited for both activities.

Section D: Professional guidelines and training (questions D1 and D2)

This section gives a list of professional associations, which are also available on the research ethics webpages. The list is not exhaustive and applicants have space to list other guidelines relevant to their work. They should read and tick **at least one** guideline to show they will follow best practice. If the project is outside the scope of the committee's expertise, it can be helpful to look through the guidance which has been ticked, in case it resolves some of the envisaged ethical or conduct issues.

Applicants should then list relevant training and must not leave this section of the form blank. Please see our ethics training webpage for information about training courses, including some online courses, is available at. The core course of the online Epigeum research integrity training is compulsory for all researchers at the University of Oxford.

All departments/ schools/ faculties are encouraged to offer or promote research ethics or integrity training to their staff and students (this can be delivered in a variety of ways, eg via online courses, specialist ethics face-to-face training or as part of a research methodology seminar).

If a project involves a particularly specialised or risky activity, researchers, particularly student researchers, must justify how they are appropriately qualified to carry out such activity. Principal researchers (see Section B question 1) are responsible for the qualification and training of all members of the project team.

For some studies with participants at risk and/ or children, researchers will need to complete the relevant Safeguarding training and a relevant risk assessment before starting their research. DRECs should ask for a copy of the Safeguarding certificate and risk assessment for their records in order to ensure that the training has been completed. For further information about Safeguarding, including links to the online training courses and risk assessment forms, please see the University's webpage on Safeguarding. However, it is not the role of the DREC (or IDREC) to review the details of risk assessments.

Section E: Signatures

A signature or email endorsement is needed from the PI, the student (if student research) and the head of department or nominee. In lieu of signatures, an email endorsement can be provided.

- The PI (and student, where applicable) should copy and paste the text from the 'Declarations and signatures of researchers' section of the CUREC 1, 2 or 3 form, or section E1 of the CUREC 1A form into an email.
- The head of department (or deputy) should copy and paste the text from the 'Acceptance by head of department/ faculty or designated nominee' section of the CUREC 1, 2 or 3 form, or section E2 of the CUREC 1A form.

Non-University members should not sign CUREC 1A forms.

DRECs should not approve a CUREC 1A application unless all relevant signatures are in place.

Why do we need a separate departmental endorsement signature?

It is important for the department/ school/ faculty to endorse the project independently, even though a departmental research ethics committee (DREC) may be reviewing it. This is because the DREC reviews the ethical issues only, whereas a departmental endorsement will approve the project design and scientific methodology, in addition to the project's ethics. By endorsing the project, departments will be able to monitor that research projects are consistent with departmental research strategy.

Supporting documentation: how to review when supplied as part of the CUREC 1A application

General advice on what kind of supporting documents applicants are expected to produce is found on the SSH IDREC application process webpage. In general, DRECs should ensure that documents are expressed clearly and simply, with age-appropriate language. Specific advice on how to design informed consent processes and write associated documents is given on CUREC's webpage on informed consent.

Researchers are encouraged to adapt the informed consent templates available on the CUREC website:

- Written and/ or oral consent process templates

- For online surveys only, researchers may adapt the combined informed consent process template in Appendix A of our Best Practice Guidance for Internet-Based Research.

Each of these sections contains downloadable templates covering all the relevant sections needed for a complete information sheet, written consent form, and oral consent script.

The informed consent templates may not be appropriate for all types of research, for example ethnographic research. In the latter case the researcher may choose instead to follow the guidelines given by the Association of Social Anthropologists of the UK and Commonwealth and provide details in their CUREC application as to how they will obtain consent as appropriate from participants in the research.

Further guidance

DRECs are welcome to contact the Research Ethics Manager or Research Ethics Administrator for advice, using the contact details available on the research ethics webpages.