Form CUREC 2

CENTRAL UNIVERSITY RESEARCH ETHICS COMMITTEE (CUREC)
Form CUREC 2 Application form

The University of Oxford places a high value on the knowledge, expertise, and integrity of its members and their ability to conduct research to high standards of scholarship and ethics. The research ethics clearance procedures have been established to ensure that the University is meeting its obligations as a responsible institution. They start from the presumption that all members of the University will take their responsibilities and obligations seriously and will ensure that their research on human subjects is conducted according to the established principles and good practice in their fields and in accordance, where appropriate, with legal requirements. Since the requirements of research ethics review will vary from field to field and from project to project, the University accepts that different guidelines and procedures will be appropriate. Please check the CUREC website to ensure that you have the correct checklist or application form for your project.

ONLY TYPE-WRITTEN APPLICATIONS WILL BE ACCEPTED.

ONLY EMAILED APPLICATIONS WILL BE ACCEPTED. PLEASE DO NOT SEND APPLICATIONS BY POST.

WHAT THIS APPLICATION FORM IS DESIGNED FOR

The **CUREC 2 application form** can be used for applications **either** to the Social Sciences and Humanities **or** to the Medical Sciences Interdivisional Research Ethics Committees (SSH IDREC and MS IDREC respectively).

The form is designed for research where certain project characteristics (e.g. type of participants, or procedures) result in a set of ***complex ethical issues***. It is expected that only in a limited number of cases will it be necessary for researchers to complete a CUREC 2 application. Therefore if unsure whether your project is complex, please check (i) on our website: http://www.admin.ox.ac.uk/curec/ (see Glossary and our Contacts); (ii) with your department; or (iii) with your departmental research ethics committee (if you have one).

The use of an ***asterisked word*** in this application form indicates a phrase defined in CUREC's Glossary.

The glossary and further information on the University's research ethics procedures are available on our website.

WHAT THIS APPLICATION FORM WILL NOT ASSESS

The application form should not be used for research with ***straightforward ethical issues*** (see Glossary). For such research, please use the CUREC 1A checklist (for applications to SSH IDREC), the CUREC 1 checklist (for MS IDREC) or the minimal risk application form (for OXTREC). To access these documents please go to our How to Apply pages at https://www.admin.ox.ac.uk/curec/apply/.

This form does not cover research governance, satisfactory methodology, or compliance with the requirements of publishers when administering their tests or questionnaires. As principal researcher, it is your responsibility to ensure that requirements in these areas are met.

CUREC does not review studies classed as ***audit*** (see Glossary and the Decision Flowchart for CUREC on our website).

Please complete the sections that follow and follow prompts to stop completion and/or submit other documents.

Please indicate your answer to all the Yes / No questions by typing 'X' in the appropriate box.

Example:		
*1. **Involvement of other ethics committees. Will you submit or have you submitted this project to another ethics committee?***	*Yes X*	*No*

SECTION A: principal researcher contact details, other researcher(s) contact details, and project description (NB must be typed not handwritten)	
__Principal researcher__ / supervisor (if student research) contact details:	
1. Title of person and name:	
2. Title and name of student (if student research):	
3. Degree programme, e.g. DPhil, BA, MPhil, BSc, MSc (if student research):	
4. Department or Institute name:	
5. Address for correspondence (if different from 4 above):	
6. University e-mail and telephone contact:	
7. Training in research ethics: please indicate what training you have received with title and date completed (online training available)	
Other researcher(s) contact details:	
8. Title of person (or people) and name(s):	
9. Department or Institute name:	
10. Address for correspondence (if different from 5 above):	
11. University e-mail and telephone contact:	
12. Role(s) in project: please give role(s), qualifications and relevant experience and degree course (if relevant):	
13. Training in research ethics: please indicate what training other researcher(s) received with title and date completed (online training available)	

Project description			
14. Title of research project:			
15. List all *__sites__* where project will be conducted:			
16. If your research involves overseas travel or fieldwork, by the time the research starts, will you have completed and returned a travel risk assessment form? (This may be necessary to ensure that the activity is covered by the University's travel insurance – see http://www.admin.ox.ac.uk/finance/insurance/travel/)	Yes	No	N/A
If no or N/A, please give more details:			
17. Anticipated duration of project:	months or	years	
18. Anticipated start date:	From: (dd/mm/year)		
19. Anticipated end date:	To: (dd/mm/year)		
20. Involvement of other ethics committees.			
Will you submit or have you submitted this project to another ethics committee?	Yes	No	
If other relevant approvals for this research are required (e.g. from other universities' ethics committees) please attach them and give more details below:			
/Section A (continued)			

SECTION A (continued): principal researcher contact details, other researcher(s) contact details, and project description (NB must be typed not handwritten)

21. Have you used any of the following to develop your application:	Yes	No

- CUREC protocols (see https://www.admin.ox.ac.uk/curec/resources/protocols/)
- Professional guidelines (see our website for a selection of professional guidelines)
- CUREC best practice guidelines

If yes, list relevant documents and give details.

If no, please explain why not below:

22. Description of the project (200 words max).

Please say why your project is important and valuable. Describe briefly your methodology. Although it's important to describe any aspect of your project which is beyond already established and accepted techniques, **we do not require a detailed scientific background unless directly relevant to ethical issues**.

SECTION B: research involving contact with human participants

If the project involves **contact** with ***human participants*** (in person or virtual), or **observation** of them, ***please complete this section (Section B).***

If the project involves **no contact** with ***human participants*** (in person or virtual) and **no observation** of them, but only use of data about them, ***please do NOT complete this section, but go to Section C.***

23. Description of participants (300 words max).

Please describe (for each different participant subgroup):

- number of participants to be recruited;
- ***defining criteria*** for participation including what type of people are sought (e.g. students, children, politicians, gang members), age range.
- How, where and by whom participants will be identified and approached to take part in the project.
  If co-researchers are conducting any part of the consent process, give their qualifications and experience.

24. Will any of your participants be ***children***?	Yes	No

If yes, please describe:

- How they are defined as children based on cultural context. I.e. the age of adolescence and adulthood varies by country.
- Any protocols or CUREC guidelines relating to children that you feel apply (if not stated at question 15). In particular see CUREC guidance on Competent Youths, (BPG 04 at https://www.admin.ox.ac.uk/curec/resources/bestpractice/) and our FAQ C11-C12 at https://www.admin.ox.ac.uk/curec/faqs-glossary/faqs/.
- In particular please state why Protocol 25 (research on children) cannot apply wholly to your project.

/Section B (continued)

SECTION B (continued): research involving contact with human participants		
25. Will ***unequal relationships*** exist between participants and those obtaining informed consent? **If yes,** describe nature of unequal relationship and how arising ethical issues will be resolved.	Yes	No
26. Will the research involve deliberate ***deception*** of participants? **If yes**, justify why deception is used, describe deception and debriefing process, and include debriefing documents in the application	Yes	No
27. By taking part in the research, will participants be at risk of prosecution? **If yes,** justify why incriminating data are sought in the research, and how risks to participants are minimized.	Yes	No
28. Will you obtain ***informed consent*** from participants according to CUREC guidelines and good practice in your discipline before participation?	Yes	No
If yes, please describe the process including whether it is oral (available as an option for applicants to SSH IDREC only) or written; and why, and how long people will have to decide about participation. You should include examples of oral scripts or written forms with your application. See https://www.admin.ox.ac.uk/curec/resources/informed-consent/. **If recruiting children** Note that children have emerging mental capacity and so cannot generally consent to research (except in the case of "Competent Youths"). In this case, you should describe the ways in which parents/guardians will give consent, and supply parental information and consent forms. Please also supply age-appropriate information for child participants and assent forms as appropriate to their age and ability to understand the "research contract". **If no**, please give a justification for why not.		
/Section B (continued)		

SECTION B (continued): research involving contact with human participants

29. Participant pathway through the research (max 400 words)

Please describe the participant's experience of the research from the point of them having given consent until the end of their involvement with researchers. This would include:

- Number, duration, frequency and type of activities/interventions/investigations
- Any potential risks or actual ill effects of participation e.g. invasive procedures, distress and how these will be minimized
- Implications for disclosure of incidental findings (and see also Section D)
- Who these risks/ill effects may affect e.g. participants, researchers, third parties
- Any reputational risks e.g. to the University

Please also describe any proposed benefits (if applicable)

To support your description please attach documentation such as:

- recruitment and advertisement material e.g. a poster or invitation letter
- informed consent documents (participant information sheets, consent forms)
- any other forms participants will need to complete e.g. blank questionnaire
- any questions they are asked (e.g. guide to interview questions or a preliminary scope of questions)

Detailed guidance about documentation is found on the CUREC website

Participant experience (split into subgroups if necessary):

Risks:

Benefits:

30. How will your project data be handled?

Your project must meet the standards laid down in the Data Protection Act (1998) with respect to the collection, use, and storage of ***personal data*** about ***human participants***.

Describe the form of data handling and storage arrangements throughout the project: at collection stage; when used/disclosed; when stored; and when destroyed.

Up until destruction, be clear about describing whether data will be non-anonymised (openly linked to the individual(s) who provided them and so fully identifiable), pseudo-anonymised (potentially linkable/identifiable), or completely anonymised (cannot be linked back to an individual/individuals by researchers, non-identifiable).

For guidance, please also refer to the University policy on the management of research data and records at http://researchdata.ox.ac.uk/university-of-oxford-policy-on-the-management-of-research-data-and-records/

Collection:

Use/disclosure (including secure transfer arrangements of data:

Storage:

Destruction:

SECTION C: research involving secondary use or disclosure of personal data[1]

NB this section of the form is not to be routinely completed by applicants. You should only complete this section if you meet the criteria below.

Please complete this section for research activity (as part or all of a project) where there is no contact with ***human participants*** (in person or virtual) and no observation of them, but only use of data about them.

Your project must meet the standards laid down in the Data Protection Act (1998) with respect to the collection, use, and storage of ***personal data*** about ***human participants***.

31. Will you seek data access agreements for these data?	Yes	No

If yes,

- list the individual(s) or organisation(s) from which information will be sourced.
- attach a copy of the agreement with the individual(s) or organisations in question.
- provide details of any conditions imposed by the organisation(s) concerning the release of the information.

If no, please explain how and when the agreement of the disclosing organisation(s) will be obtained.

Individuals / organisations from which data has been sourced:

Any conditions:

32. Could these data be linked back to an individual or individuals?	Yes	No

If yes, please explain and describe:

- why data cannot be collected in a way which prevents linkage with an individual/individuals
- say how individual consent was obtained for the collection, use or disclosure of linkable data

If no (i.e. you can't link these data back to individuals), continue to question 33.

Linkage:

Consent for linkable data:

33. How are project data handled?

For both the sourcing and use/disclosure of data, describe the form of storage arrangements throughout the project: at the sourcing stage; when used/disclosed; when stored; and when destroyed.

Up until destruction, be clear about describing whether data will be non-anonymised (openly linked to the individual(s) who provided them and so fully identifiable), pseudo-anonymised (potentially linkable/identifiable), or completely anonymised (cannot be linked back to an individual/individuals by researchers, non-identifiable).

For guidance, please also refer to the University policy on the management of research data and records at http://researchdata.ox.ac.uk/university-of-oxford-policy-on-the-management-of-research-data-and-records/

How data was obtained:

Use/disclosure (including secure transfer arrangements of data:

Storage:

Destruction:

34. How will the privacy of individuals be respected in any publication arising from this project?

[1] From Glossary: "*In this context an individual discloses information when he/she releases information to organisations or individuals which / who are outside of the research project*."

SECTION D: miscellaneous issues – conflicts of interest, peer review, adverse events and monitoring		
35. Do you or other researchers have a potential or actual ***conflict of interest*** in this project's conduct or outcomes?	Yes	No
If yes, state nature of conflict (financial or otherwise), and any potential risks arising from this.		
36. Has the project been subject to ***peer review***?	Yes	No
If yes, please explain by whom and give outcome. **If no**, explain why not.		
37. How will the project be **monitored / overseen** and by whom? Please describe monitoring / oversight and reporting arrangements with particular attention to: • student research e.g. supervisory process • ethical issues • adverse events e.g. incidental findings, injury to participants, leaks of data, protocol breaches.		
38. How will you disseminate and feedback project outcomes at the end of the research? Please describe your plans with respect to participants as well as public dissemination plans, e.g. in journals and conferences.		

Section E. Signatures and declarations

39. **Declaration by researchers**

Full project title:

I/We, the researcher(s) agree:

- To start this research project only after obtaining approval from IDREC/CUREC;
- To carry out this research project only if funding is adequate to enable it to be carried out according to good research practice and in an ethical manner;
- To provide additional information as requested by IDREC/CUREC before approval is secured and as research progresses;
- To maintain the confidentiality of all data collected from or about project participants;
- To notify IDREC in writing immediately of any proposed change which would increase the risks that any participant is exposed to and await approval before proceeding with the proposed change;
- To notify IDREC if the principal researcher on the project changes and supply the name of the successor;
- To notify IDREC in writing within seven days if any serious *__adverse event__* occurs in the course of research;
- To use data collected only for the study for which approval has been given;
- To grant access to data only to authorised persons; and
- To maintain security procedures for the protection of personal data, including (but not restricted to): removal of identifying information from data collection forms and computer files, storage of linkage codes in a locked cabinet and password control for access to identified data on computer files.

Signed by principal researcher/supervisor: ……..

Print name (block capitals): …….. **Date**: ……...

Signed by student (for student projects):..……

Print name (block capitals): …….. **Date**: ……...

Signed by associate/other researcher:..……

Print name (block capitals): …….. **Date**: ……...

/Section E (continued)

Section E (continued). Signatures and declarations

40. Certification by *principal researcher*/supervisor and head of department

Full project title:

Certification by *principal researcher*/supervisor

- I accept responsibility for the conduct of this research project.
- I certify that all researchers and other personnel involved in this project are appropriately qualified and experienced or will undergo appropriate training to fulfil their role in this project.

Signed by ***principal researcher*/supervisor**: ……..

Print name (block capitals): …….. **Date**: …….

41. Acceptance by head of department (or other senior member of the department if the principal researcher is the head of department)

- I have read the research project application named above.
- On the basis of the information available to me, I judge the ***principal researcher***/supervisor and ***student researcher*** (if applicable) to be aware of their ethical responsibilities in regard to this research.
- I am satisfied that the proposed project has been/will be subject to appropriate peer review and is likely to contribute to existing knowledge and/or to the education and training of the researcher(s) and that it is in the public interest.

Signed by head of department/faculty or nominee: ..……..

(example nominees include Chair of DREC, or, for student projects, Director of Graduate Studies / Undergraduate Studies)

Print name (block capitals): …….. **Date**: …….

SECTION F: Final check

Please use this section to check that you have completed the following tasks:	**Please type 'X'**
Have you completed Sections A-E?	
Have you included copies of any documentation produced in support of your application? **If the appropriate supporting documentation is not included with your application, you will then be asked to provide this separately. This may well delay the ethical review process, and thus the start of your research.**	
Have you included copies of data access agreements with third parties (see Section C, question 31) if appropriate?	
Have you included debriefing documents for projects involving deliberate deception?	
Have you checked that all documents for participants are clear and easy to read (pilot-testing with lay readers, or using reading-age checking software as appropriate)?	
Have you signed as principal researcher and gathered signatures of the student (for student research) and department nominees as appropriate?	
Have you declared conflicts of interest (if any)? (See Section D)	
Are all pages (including supporting document attachments) numbered?	
Have you defined all technical terms and abbreviations used?	