**University of Oxford**

**FAQs in sections C & D**

**CENTRAL UNIVERSITY RESEARCH ETHICS COMMITTEE (CUREC)**

Not all research project leaders need to fill in this form. **Before starting work on this form**, please fill in CUREC’s checklist (CUREC/1 or 1A) which will show if you need to complete this form. Please also ensure you have consulted the following CUREC guidance documents available on the [CUREC website](https://www.admin.ox.ac.uk/curec/guidanceondocumentsforparticipants/)) :

* [Guidance on approval process](https://www.admin.ox.ac.uk/curec/approval/)
* [Glossary](https://www.admin.ox.ac.uk/curec/glossary/)
* [FAQs](https://www.admin.ox.ac.uk/curec/faqs)

Definitions of terms marked with an asterisk are to be found in CUREC’s glossary and guidance.

SECTION 1: PROJECT TITLE, RESEARCHERS, AND CONTACT DETAILS

**1.** **Person to whom IDREC/CUREC should direct correspondence:**

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| **\*Principal investigator/supervisor/student researcher**  **FAQ C2**  Title and name: |
| Appointment: |
| Department: |
| Institution: |
| Address:  Phone:  Fax: |
| e-mail: |
| Please indicate what training on research ethics you have received, e.g. the title of the online or in-person course, and date completed (online training available at [www.admin.ox.ac.uk/researchsupport/integrity/human/](http://www.admin.ox.ac.uk/researchsupport/integrity/human/)): |
| **FOR STUDENT RESEARCH PROJECTS ONLY**  Name of Supervisor: |

2. Full project title and proposed starting date:

**FAQs C3&C7**

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| **Office use only: IDREC Ref. No**.\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date of Approval: / /**  Application date: / / Approval Period: from / / to / /Signature of IDREC approver: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Name (printed) and position of approver: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date applicant informed of approval: / / |

3. Are you submitting this project to another ethics committee or has it been previously submitted to an ethics committee?

Yes - provide details.

No

*If other relevant approvals for this research are required (e.g. from other universities’ ethics committees) please attach them.*

4. Have you made use of professional/CUREC guidelines in framing your research project and preparing documentation?

Note: the CUREC guidelines are available online (<http://www.admin.ox.ac.uk/curec/oxonly/protocols/guidelines.shmtl>) or by emailing [curec@admin.ox.ac.uk](mailto:curec@admin.ox.ac.uk)

Yes - provide details.

No – explain why not.

5. Researchers involved in this project

Please supply one completed copy of this box for each researcher*.*

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| --- |
| **\*Associate researcher/student researcher**  Title and name: |
| Appointment: |
| Department: |
| Institution: |
| Address:  Phone: Fax: |
| e-mail: |
| Role in this project:  Qualifications and relevant experience for this project:  Degree course (if relevant):  Will this researcher be approved by the principal researcher as competent to obtain \*informed consent from participants? |
| Please indicate what training on research ethics the researchers involved with this study have received, e.g. the title of the online or in-person course, and date completed (online training available at [www.admin.ox.ac.uk/researchsupport/integrity/human/](http://www.admin.ox.ac.uk/researchsupport/integrity/human/)): |

SECTION 2: PROJECT DESCRIPTION

6. Description of project

Please give a description (300-800 words) of your project to supplement the information already provided in Section A of the checklist (CUREC/1), detailing those aspects of the project which involve \*human participants, particularly any aspect which is beyond already established and accepted techniques. Please attach all other documents (e.g. questionnaire, recruitment advertisements, participant information, and consent forms) that you plan to use in the study. **Please note that detailed scientific background is not required unless directly relevant to ethical issues.**

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7. Literature search

If the research involves significant risk to the human participants please describe what literature searches have been undertaken to obtain information to aid risk reduction/management.

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SECTION 3: RESEARCH INVOLVING CONTACT WITH \*HUMAN PARTICIPANTS

If the project does NOT involve contact with\*human participants, but only use of data about them, do NOT complete this section, but go to Section 4. If you are not completing Section 3 please delete it from your application to save paper.

8. Description of participants

How many participants will be involved in the project?

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9. Details of participants

**(a)** What types of people will be recruited e.g. students,\* children, people with learning disabilities? [Please see the [Glossary](https://www.admin.ox.ac.uk/curec/glossary/) on the CUREC website for information on how the meaning of \*capacity to consent has been altered by the Mental Capacity Act 2005]

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**(b)** What will be the age range of participants?

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**(c)** How will the competence of participants to give \*informed consent be determined?

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**(d)** What are the \*defining criteria for participation in the study?

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10. Recruitment of participants

**(a)** Describe how, where, and by whom participants will be identified, approached, and recruited.

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**(b)** If your research involves any use of \*personal data obtained from a \*third party, describe the steps you have taken to ensure that the \*third party has arrangements in place to permit disclosure.

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**(c)** Will any \*unequal relationships exist between anyone involved in the recruitment and the potential participants?

Yes

No

If yes:

(i) Describe the nature of the unequal relationship.

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(ii) Explain how ethical problems arising from the unequal relationship will be resolved.

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**(d)** Describe any \*financial or other rewards which will be offered to participants.

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11. \*Participant information

It is essential that written information is easily understandable by participants. Failure to provide this information in appropriate lay language is the most frequent reason for delays in ethical approval.

**(a)** Will participants receive **written** information about the project before giving their consent?

Yes - please attach.

No - give reasons.

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**(b)** Who will give the participants the information and how?

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**(c)** Does the research involve deliberate \*deception of participants?

Yes- explain why the real purpose of the research needs to be concealed and how and when participants will be told of the deception.

No

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**(d)** Please describe the basis on which you have decided how long participants will have to think about the information provided before giving consent.

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12. \*Informed consent

**(a)** Will you obtain written consent?

Yes - please attach \*consent form.

No - explain how consent will be obtained and recorded and why this method is used.

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**(b)** If participants are unable to give valid consent, how and from whom will you obtain consent? [Please see the [Glossary](https://www.admin.ox.ac.uk/curec/glossary/) on the CUREC website for information on how the meaning of \*capacity to consent has been altered by the Mental Capacity Act 2005]

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**(c)** List those researchers who will, with the authorisation of the principal researcher (or supervisor in the case of student researchers), secure the consent of participants.

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13. Consequences of participation

**(a)** What are the potential risks or actual ill effects of participation (if any) e.g. invasive procedures, distress, deception etc, and what will be done to minimise these risks

(i) to the participants?

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(ii) to the researchers?

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(iii) to others (e.g. the university, family)?

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**(b)** Is there a need for support or counselling?

Yes - describe the form of support or counselling and how, when, and by whom it will be conducted.

No

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1. Is there a need for debriefing or follow-up discussion?

Yes - describe the form of debriefing or follow-up discussion and how, when, and by whom it will be conducted.

No

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1. Are there any potential benefits to the participants?

Yes - describe them below.

No

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14. \*Adverse events

How will adverse events be monitored and reported?

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15. Monitoring

Explain how and by whom (e.g. supervisor in the case of student research projects) the ethical aspects of the project will be monitored to ensure that they conform to the procedures set out in this application.

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SECTION 4: RESEARCH INVOLVING COLLECTION, USE, OR \*DISCLOSURE OF \*PERSONAL DATA

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.

Please delete questions or parts of questions that you are not required to answer to save paper***.***

**16. Need I complete this section?**

Does the project involve the collection, use or disclosure of personal information including sensitive and/or genetic information?

No – you need not complete this section. **Go to Section 5.**

Yes – you must answer questions in this section. **Go to Question 17.**

17. Type of activity proposed

Does the research involve:

**(a)** disclosure of personal information?

Yes

No

**(b)** collection of personal information?

Yes – **go to Question 18.**

No – **go to Question 20.**

18. Collection of information directly from individuals

**(a)** Does the project involve collection of information directly from individuals about themselves?

No – **go to Question 19.**

Yes – answer the following questions:

**(b)** Do the \*participant information and the \*consent form include the following:

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| --- | --- |
| the name of the study? | Yes  No |
| the name and status (e.g. doctoral student) of the researcher collecting the information and how to contact him/her? | Yes  No |
| the purpose of the study? | Yes  No |
| declarations that the participant  has read the participant information sheet? | Yes  No |
| has had the opportunity to ask questions about the study and has received satisfactory answers to questions, and any additional details requested? | Yes  No |
| understands that s/he may withdraw from the study without penalty at any time by advising the researchers of this decision? | Yes  No |
| understands that this project has been reviewed by, and received ethics clearance through, the University of Oxford Central University Research Ethics Committee? | Yes  No |
| understands who will have access to personal data provided, how the data will be stored; and what will happen to the data at the end of the project? | Yes  No |
| agrees to participate in this study? | Yes  No |
| understands how to raise a concern and make a complaint? | Yes  No |

If you answered ‘no’ to any of these questions, explain why this information has not been included in the participant information and the consent form.

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**(c)** Are the consent form and participant information on headed letter paper which bears the name of the University and the name and address of the department to which the principal researcher is attached?

Yes

No - explain why not.

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**(d)** Are the participant and the researcher who secures the consent required to sign, print and date their names?

Yes

No -explain why not.

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19. Collection of information from a third party

**(a)** Does the project involve collection of information about an individual from a source other than the individual?

No – **Go to Question 20.**

Yes – complete the following sections.

**(b)** List the individuals or organisations from which information will be collected. If information will be collected from more than one source, state which information or records will be collected from each source.

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**(c)** Have all organisations from which the information is to be collected agreed to provide the information or to allow access to the information?

Yes - attach a copy of each letter of agreement. Provide details of any conditions imposed by the organisation(s) concerning the release of the information.

No - explain how and when the agreement of the disclosing organisation will be obtained.

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**(d)** Will the information be potentially or actually ascribable to an individual when it is received?

No – **go to Question 20.**

Yes – answer the following questions:

**(e)** Does the project involve collection of information without the consent of the individual to whom it relates?

No – **go to Question 20.**

Yes – answer the following questions:

**(f)** Give reasons why information will not be collected in a way which prevents its ascription to an individual.

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**(g)** Why will consent not be obtained from the individual(s) whom the information describes? [Please see the [Glossary](https://www.admin.ox.ac.uk/curec/glossary/) on the CUREC website for information on how the meaning of \*capacity to consent has been altered by the Mental Capacity Act 2005]

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20. Form in which data are to be stored

Are the data to be kept

**(a)** with an open identifier, i.e. in non-anonymised form  Yes  No

**(b)** as anonymised but potentially identifiable data  Yes  No

**(c)** as anonymised, non identifiable data  Yes  No

21. Use or disclosure of information about individuals

**(a)** Does the project involve the use or disclosure of information potentially or actually ascribed to an individual?

No – **go to Question 22.**

Yes – answer the following questions.

**(b)** Does the project involve use or disclosure of information without the consent of the individual whom the information describes?

No – **go to Question 22.**

Yes – answer the following questions:

**(c)** What are the specific purposes for which the information will be used?

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**(d)** Is the purpose for which the information will be used related to the purpose for which the information was originally collected?

Yes – give details.

No – give details.

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**(e)** Describe in detail which information or records will be disclosed to which organisations.

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**(f)** Give reasons why information will not be used or disclosed in a way which prevents its ascription to an individual. (If the answer is the same as for question 19 (f), write ‘as above’.)

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**(g)** Why will consent not be obtained from the individual(s) whom the information describes? (If the answer is the same as for question 19 (g), write ‘as above’.)

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**(h)** Explain why the proposed use or disclosure of information is in the public interest. The public interest in the proposed research must substantially outweigh the public interest in respecting individual privacy.

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22. Data collection, storage, and disposal

**(a)** How many records will be collected, used or disclosed? Specify the information that will be collected, used, or disclosed e.g. date of birth, medical history, number of convictions.

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| Number of records:  Type of information: |

**(b)** How, where, and under what security arrangements will electronic and paper data be stored? Who will have and control access to the information?

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**(c)** When, how and by whom will the information be disposed of?

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**(d)** How will the privacy of individuals be respected in any publication arising from this project?

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(e) Have you explained in the \*participant information and \*consent form that maintenance of confidentiality of information is subject to normal legal requirements?

Yes

No – explain why not.

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23. Adverse and unforeseen events

How will adverse and unforeseen events relating to the collection, use, or disclosure of information be managed, monitored and reported?

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SECTION 5: MISCELLANEOUS ISSUES

24. \*Conflict of interest

**(a)** Do researchers on this project have a financial or other interest in its conduct or outcomes?

Yes – give details.

No

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**(b)** If there is a conflict of interest, have you declared it in your \*participant information and \*consent form?

Yes

No – explain why not.

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**(c)** Are there any other potential conflicts of interest e.g. research findings that could compromise the researcher’s relationship with the university?

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**25. \*Peer review**

Has this project been peer reviewed?

Yes – explain by whom (e.g. by a, tutor, supervisor, funding body etc) and with what outcome.

No – explain why not.

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26. Funding

List all bodies and individuals from whom funding has been or will be sought.

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| --- | --- | --- | --- |
| Source | Amount in £ | Status of Funds Available Applied for | |
|  |  | Yes  No | Yes  No |
|  |  | Yes  No | Yes  No |

27. Reporting of results

**(a)** Will the project outcomes be made public at the end of the project?

Yes – describe the intended report and how and to whom it will be made available.

No – explain why not.

**(b)** Will a report(s) of the project outcomes (for example, individual or group data) be made available to participants at the end of the project?

Yes – describe report and how it will be made available.

No – explain why not.

N/A

28. Declaration by researchers

Full project title:

I/We, the researcher(s) agree:

1. To start this research project only after obtaining approval from IDREC/CUREC;
2. 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;
3. To provide additional information as requested by IDREC/CUREC before approval is secured and as research progresses;
4. To maintain the confidentiality of all data collected from or about project participants;
5. 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;

**FAQs F1&F2**

1. To notify IDREC if the principal researcher on the project changes and supply the name of the successor;

**FAQ F3**

1. To notify IDREC in writing within seven days if any serious \*adverse event occurs in the course of research;
2. To use data collected only for the study for which approval has been given;
3. To grant access to data only to authorised persons; and
4. 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/student researcher:…………………… ……

Date:…………………

Print name (block capitals)…………………………………………………………………

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

Date:…………………

Print name (block capitals)…………………………………………………………………

Signed by associate/other researcher: ………………………………………………………

Print name (block capitals)……………………………………………………………………

Date ………………

29. Certification by \*principal researcher/supervisor/student researcher and head of department

Full project title: ……………………………………………………………………………

Certification by \*principal researcher/supervisor/student researcher

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/student researcher:

…………………………………………………………………………………………………

Date:…………………

Print name (block capitals)…………………………………………………………………

Acceptance by head of department/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/student researcher to be aware of her/his 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.

Name of head of department/other senior member of the department(e.g Chair of DREC, Director of Graduate Studies for student projects):

…………………………………………………………………………………………………

Signature …………………………………………………… Date……………….….…

FINAL CHECK

To prevent delay please check each of the following before submitting the application.

Have you answered all relevant questions in Sections 1-5?

Have you defined all technical terms and abbreviations used?

Have you included all questionnaires and participant information, consent forms, advertisements,   
and surveys to be used?

Have you included all relevant approvals and supporting letters?

Have you declared all potential conflicts of interest?

Are all pages (including appendices and attachments) numbered?

Have you completed the declaration by researcher(s)?

Have you completed the certification by principal researcher and head of department?

Revised March 2012