Research Ethics at Oxford – your chance to be an ethics committee member

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Structure of this session

**Research ethics in context** – guidelines and policies (national and internal)

**Why research ethics committees?**

Oxford REC structure
- Central University Research Ethics Committee (CUREC)
- Inter-divisional Research Ethics Committees (IDREC/OxTREC)
- Departmental Research Ethics Committees (DRECs)

**What needs CUREC review?**

Flowchart
Structure of this session (cont)

How to apply for ethical review
- Approved Procedures
- What we can’t accept
- Tips for quick approval
- Supporting documents and “informed consent” (incl. templates)

Tools
Three case studies: choose either Social Sciences, Medical Sciences or Oxford Tropical Medicine

Your questions
The Concordat to Support Research Integrity

Maintaining the highest standards of research integrity

Researchers will:
• ensure that all research is subject to active and appropriate consideration of ethical issues
• comply with ethical, legal and professional frameworks, obligations and standards as required by statutory and regulatory authorities, and by employers, funders and other relevant stakeholders

Employers of researchers are responsible for:
• having clear policies on ethical approval available to all researchers
• making sure that all researchers are aware of and understand policies and processes relating to ethical approval
University Policy on the Ethical Conduct of Research Involving Human Participants and Personal Data

Extract....

• The University is **committed** to ensuring that research involving human participants and personal data conducted on University premises or using University facilities or by University researchers is carried out to high ethical standards

• The University meets this commitment by:
  • identifying and reviewing all research involving human participants and personal data in **proportion to the level of risk**, except where the ethical standards of that research are more appropriately secured by another recognised approval procedure, for example that of the National Health Service.
  • [www.admin.ox.ac.uk/curec/policystatement](http://www.admin.ox.ac.uk/curec/policystatement) - applies to all research conducted by members of the University since Oct 2006
Justification for the Oxford RECs

“Reasonable disagreement”

The **REC system enables decisions to:**

- Be discussed from a range of perspectives
- Occur with fair process
- Meet institutional requirements
- Be adapted to context
Oxford’s Research Ethics Committees


Central University Research Ethics Committee (CUREC)

- Social Sciences and Humanities Interdivisional (SSH IDREC)
- Medical Sciences (MS IDREC)
- Oxford Tropical REC (OXTREC)

Project

NHS patients?
- Yes → Clinical Trials and Research Governance (University Sponsor)
- No → NHS National Research Ethics Service

NHS staff, facilities or data?
- Yes → CTRG (NHS Trust permission)
- No → Central University Research Ethics Committee (CUREC)

14+ Departmental RECs (DRECs)*
What needs CUREC review?

- Research involving human participants or personal data
- Fresh data collection (even unidentifiable!)
- Generalisable, generally applicable enquiry/results
Decision flowchart: My Project Involves Human Participants and/or Personal Data. Do I need to apply to CUREC?

**Project Scenario**

- Using data collected before the project was formulated, where data are fully anonymous and not identifiable by researchers (see full A3)
  - **Outcome:** Ethical approval not required

- Conducting project on behalf of, or at request of an institution, company or service provider?
  - **Outcome:** Apply to CUREC (additional approvals may also be required)

- Project aims primarily to monitor or improve performance of that institution/company/provider?
  - **Outcome:** Apply to CUREC (additional approvals may also be required)

- Conclusions are wholly or primarily applicable to that institution/company/provider?
  - **Outcome:** Apply to CUREC (additional approvals may also be required)

- Is there potential that the project, or material from it, be published?
  - **Outcome:** CUREC review not required (alternate approvals may be required)

- Just internally published? e.g. internal company report, confidential report, funding case development, research methods development
  - **Outcome:** CUREC review not required (alternate approvals may be required)

- Planned for external, publicly accessible publication? e.g. thesis deposited online in the Oxford Research Archive, conference presentation, peer-reviewed journal publication
  - **Outcome:** Apply to CUREC

- **Outcome:** Ethical approval not required

Latest revision August 2016
How to apply for ethical review

See [www.admin.ox.ac.uk/curec/apply/](http://www.admin.ox.ac.uk/curec/apply/)

- “Straightforward issues” application (CUREC 1/1A/minimal risk form and supporting documents)
- Full / “Complex issues” application (e.g. CUREC 2 form and supporting documents)

CUREC 2s may be needed if:
- No informed consent
- Using severe deception (check our ‘Approved Procedure’)
- High participant risk
- Sensitive topics (abuse), criminal activity
- Other legal breaches (data)
- Not fully covered by one ‘Approved Procedure’

Review timeframes differ!
Straightforward (CUREC 1/1A/OxTREC minimal risk) = 30 days
Complex (for CUREC 2s) = 60 days
Tools: CUREC “Approved Procedures” (formerly “CUREC Protocols”)

www.admin.ox.ac.uk/curec/resources/protocols/

• “Bridging step” between CUREC 1A and 2
• Keep review within CUREC 1A
• Standardise ethical conduct in specialised areas, e.g. child research
• Use procedure in harmony with study
We can’t accept

• **Retrospective applications** ("I’ve already started / finished...")

• **Unsigned applications** (We need the applicant’s signature, supervisor’s signature (if applicable), and department signature (e.g. Head of Department, Director of Graduate Studies, etc)

• **Handwritten copies or other hard copies of applications**
Tips for quick approval

• Download the latest version of the application forms from the CUREC website. Check [www.admin.ox.ac.uk/curec/apply/](http://www.admin.ox.ac.uk/curec/apply/) first to see who you will have to apply to: the SSH IDREC, a DREC, the MS IDREC or OxTREC?

• Then, complete first filter sections of the relevant CUREC 1, CUREC 1A checklist or OxTREC minimal risk form first to see if you need to apply using a more complex application form instead. (i.e. CUREC 2 form for MS IDREC or SSH IDREC studies, or full review documents for OxTREC studies.)

• Allow enough time for the ethics approval process.

• Get the correct signatures (email chain or “wet ink”)
Tips for quick approval (cont.)

• **Always supply supporting documents**, including **Informed Consent** process documents ([www.admin.ox.ac.uk/curec/resources/informed-consent/](http://www.admin.ox.ac.uk/curec/resources/informed-consent/))

• Spend **time and care** on your application (e.g. **tailor** your forms/scripts to the right target audience; **proofread**)

• **If you have a DREC**, please send your application and supporting documents to the DREC in the first instance. CUREC 2s will only be reviewed by the SSH IDREC once the DREC is satisfied with the application.
What are “Supporting documents”?

- Participant Information Sheet / Script – please adapt our templates
- Consent Form / Script - our templates can be adapted
- Advert or recruitment email
- Questionnaires / Survey / Interview script (if applicable – scope is fine)
- Debriefing sheet (if applicable)

All in **simple, lay language** (aim at 12-year olds...)

See [www.admin.ox.ac.uk/curec/resources/informed-consent/](http://www.admin.ox.ac.uk/curec/resources/informed-consent/) for further info
What is Informed Consent?

Written or oral; staged or combined
Cornerstone of good practice in research involving human participants
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Basics to cover in the Participant Information Sheet/Script

- Purpose
- Procedures
- Participants’ rights
- Data handling
- Publication arrangements
- Complaints
- Contacts
- Risks

These are all covered in our templates on www.admin.ox.ac.uk/curec/resources/informed-consent/
The Consent form: Participant understands...

- Purpose of Study
- Contents of Participant Information Sheet
- Study has CUREC Ethics Approval
- Right to Withdraw
- Data Handling and Publication Plans
- Risks
- How to Raise a Concern / Complain
- Consent to being photographed / audio / video recorded
- Consents to Study Participation
- Contacts

These are all covered in our templates: [www.admin.ox.ac.uk/curec/resources/informed-consent/](http://www.admin.ox.ac.uk/curec/resources/informed-consent/)
Central University Research Ethics Committee (CUREC)

Human Participants in Research

The University is committed to ensuring that its research activities involving human participants are conducted in a way which respects the dignity, rights, and welfare of participants, and which minimises risk to participants, researchers, third parties, and to the University itself.

In accordance with its policy on research involving human participants and personal data, the University requires that all such research be subject to appropriate ethical review.

The Central University Research Ethics Committee (CUREC) has overall responsibility for the development of this policy and for the University’s ethical review process. Below is more information about CUREC and the CUREC application process as well as related training and resources available to University researchers.

How to apply for ethical review

Information about which committee to apply to, and latest CUREC forms

Resources

Protocols, Informed Consent templates, Best Practice Guidance

About us

Structure of University committees

FAQs and Glossary

Advice on applying to the National Research Ethics Service, for review by an NHS research ethics committee, is available from the University’s Clinical Trials and Research Governance team.

Contacts

Ethics committee contacts

Clinical Trials and Research Governance Team

Related links

CUREC current membership

CUREC terms of reference

Research integrity and ethics

Clinical Trials and Research Governance (CTRG)

MS IDREC application process

SSH IDREC application processes

OxTREC application processes
Case study 1: Social Sciences

Louise is a DPhil student at Oxford, but originally from Uganda. Her research examines the impact of a government health education programme on the lives of those at risk of getting HIV in a rural Ugandan village. Her focus is on adolescents in the family context. She will spend time observing and interviewing people within their family and social (family friend) settings.

No formal consent process will be adopted, instead she will follow local practice to get permission to spend time with each family. She plans to offer each family a small financial reward for their participation in the research.

The project has been reviewed by Louise’s supervisor at Oxford. It has also been reviewed by the local Ugandan University research ethics committee (REC) and has been accepted.

What are the ethical and governance issues for Oxford University?
Case study 2: Medical Sciences

Mark is a DPhil student at Oxford.

His research examines the impact of pain stimulation on the levels of cortisol, a stress hormone, in human saliva. His research aim is to determine whether pain causes stress.

Participants will be a mix of healthy volunteers (any age) and NHS staff. He will invite participants to a University of Oxford laboratory, where they will receive pinprick pain stimuli of increasing intensity. Following each stimulus, a saliva sample will be taken for cortisol analysis. Participants will then be interviewed about their experiences.

He plans to record the interviews and will offer each participant a small financial reward for their participation in the research.

The project has been reviewed by Mark’s supervisor at Oxford.

What are the ethical and governance issues for Oxford University?

Who would need to approve this study?
Case study 3: Oxford Tropical Medicine Study

An Oxford research group based in Kenya wishes to carry out a study to explore girls’ experiences of teenage pregnancy in Kenya. They are interested in the experiences of girls from poor, rural backgrounds. They plan to recruit 30 teenage girls by visiting villages, talking to parents and their daughters, and inviting the daughters to enrol on the study. Parents will be asked to sign a consent form permitting their daughters to join the study. The participants are meant to verbally respond to a questionnaire, which will be administered by a member of the research team. The questions will cover personal questions and topics such as rape, incest and abortion. The participants also should take part in a focus group in which they will discuss their experiences of teenage pregnancy. The researchers would like to video record this. Participants will be rewarded for taking part in the study with a packet of condoms. The company that makes the condoms is funding the study. These condoms are not currently for sale in Africa, but the company is very keen to extend its market to this area of the world.

Discuss the ethical implications of this study.
Any questions?