# Research Ethics Handbook

# 2018-2019

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**Research Ethics Officer**

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# INTRODUCTION

**This handbook explains the process for obtaining ethics approval for staff and students the in the Faculty of Health and Life Sciences.** It applies to staff and students intending to undertake primary research, secondary data analysis, audit or a service evaluation involving human participants or their data.

There is some minor variation in the way applications are managed at Departmental level, staff and students in the Department of Psychology, the Department of Medical Sciences and the Department of Sport and Life Sciences (Nutrition, Movement Science, Sport, Coaching and Physical Education Programmes) should refer to the guidance specific to their Department. For further guidance about the ethics review and approval processes, please contact the Faculty Research Ethics Officer for your Department, as below.

**Departmental Research Ethics Officers (DREOs)**

| | | |
|---|---|---|
| Kellie Tune | • Faculty Research Ethics Officer<br>Marston Road Campus<br>Jack Straw's Lane<br>Marston<br>OX3 0FL | frec@brookes.ac.uk<br>01865 48 5276 |
| Sue Schutz | • Research Ethics officer for School of Nursing and Midwifery | seschutz@brookes.ac.uk uk (or frec@brookes.ac.uk for applications)<br>01865 48 8125 |
| Jo Brett | • Research Ethics officer for School of Nursing and Midwifery | jbrett@brookes.ac.uk (or frec@brookes.ac.uk for applications)<br>01865 48 2696 |
| Roger Ramsbottom | • Research Ethics officer for Department of Sport, Health Sciences and Social Work<br>• Research Ethics officer for Department of Biological and Medical Sciences and the Department of Sport, Health Sciences and Social Work. | rramsbottom@brookes.ac.uk<br>01865 48 3265 |
| Emma Davies<br>Or<br>Clare Rathbone | • Research Ethics officer for Department of Psychology, Health and Professional Development | edavies@brookes.ac.uk<br>OR<br>crathbone@brookes.ac.uk |

# FACULTY OF HEALTH AND LIFE SCIENCES ETHICS APPROVAL PROCEDURES

Oxford Brookes University devolves the process of research ethics review to individual Faculties. Each Faculty has in place procedures for the review and approval of projects involving human participants, human data or material (see Appendix 1).

The University and the Faculty of Health and Life Sciences require all researchers to adhere to the University Code of Practice on Ethical Standards for Research Involving Human Participants - https://www.brookes.ac.uk/Research/Research-ethics/Research-ethics-for-research-involving-human-participants---code-of-practice/ and to maintain high standards in the conduct of their research (see the University Code of Practice for Academic Integrity at: https://www.brookes.ac.uk/research/policies-and-codes-of-practice/).

Research projects conducted by taught undergraduate and taught postgraduate students are reviewed and approved at Departmental level (see procedure below).

Research projects by staff and PhD students are reviewed and 'signed-off' by the relevant Departmental Research Ethics Officer before being submitted to the University Research Ethics Committee for approval (see Appendix 2 for UREC Committee meeting dates). The only exception to this is where a project for research, service evaluation or audit involves NHS staff or service users and / or their data. In this case, the project must be reviewed and approved by the Faculty Research Ethics Committee (FREC) prior to submission to the NHS Research Ethics Service (see page 5).

**PLEASE NOTE: Ethical approval MUST be obtained to conduct any research with human participants before data collection takes place. Failure to do this breaches University regulations and is a disciplinary matter (see University Regulations C.1 *Student conduct regulations and procedures,* paragraph 2.2.3 available at: http://www.brookes.ac.uk/regulations/current/appeals-complaints-conduct/ ).**

## Departmental* Review Procedure (Non-NHS / Social Care Research)

### Applications from Undergraduate / MSc / MA students

Undergraduate / MSc / MA students in a health care related discipline i.e. nursing, midwifery, social work, public health, physiotherapy, osteopathy, rehabilitation and occupational therapy, conducting research outside of the NHS should complete an **E2D application form** (see http://www.brookes.ac.uk/Research/Research-ethics/Ethics-review-forms/) and submit this to their relevant Departmental Research Ethics Officer. These applications are reviewed and approved by the Departmental Research Ethics Review Group (DRERG). If conducting secondary data analysis, please follow the same procedure but use the relevant form (see p.6)

### Applications from Staff / MPhil / PhD / EdD students

These applications must be reviewed and 'signed-off' by the Departmental Research Ethics Officer before they are forwarded to the University Research Ethics Committee for review. An **E2U application form** (see https://www.brookes.ac.uk/research/research-ethics/forms-and-templates/) should be completed and sent to your relevant Departmental Research Ethics officer for feedback three weeks before the UREC meeting. Once 'signed off' the application can be forwarded to the University Ethics Committee (UREC) for review. For UREC meeting dates for 2018/2019, see Appendix 2.

## Faculty of Health and Life Sciences Research Ethics Committee (FREC)

The FREC is a sub-Committee of the Faculty Research Knowledge and Exchange Committee (FRKEC).

The H&LS FREC receives and reviews applications **from all Departments across the Faculty** for research involving:

- **The NHS National Research Ethics Service (NRES)** i.e. research involving past and present NHS or Social Care service users (including their relatives and carers, tissue samples or information).
- **Private Patients**
- An application to any other **external Research Ethics Committee** e.g. Local Authority, Ministry of Defence Research Ethics Committee

**Although audits and service evaluations do not require NRES review, they still require permission from the relevant NHS Trust R&D Department or HRA approval.** Applications to conduct a clinical audit or a service evaluation within the NHS or in Social Care should be submitted to the relevant Departmental Research Ethics Officer for review. This is to ensure that such projects are categorised correctly (according to NRES criteria) and the applicant is permitted to access the data.

The Chair of the FREC is Kellie Tune. Committee members are drawn from each Department within the Faculty to provide a range of subject knowledge combined with methodological expertise. In order to meet the requirements of the NRES, both the scientific and ethical dimensions of the research are reviewed by this Committee.

The Committee meets every 3-4 weeks throughout the year, except during August (for FREC meeting dates for 2018/2019 see Appendix 3).

The Chair communicates the outcome of the meeting to the applicant, in writing.

A maximum of 8 applications can be reviewed at any one meeting. This is on a 'first come, first served' basis. If this number is exceeded, the applicant will be informed and the application will be reviewed at the next Committee meeting.

# MAKING AN APPLICATION TO THE FREC / DRERG

An application should be made by completing one of the following forms:

| Type of study | Form | How accessed | Review process |
|---|---|---|---|
| Research involving past or present NHS / Social Care service users, their relatives / carers, tissue samples or information | Integrated Research Application Service (IRAS) form | http://www.myresearchproject.org.uk | Application reviewed by FREC, then forwarded to NRES for review and HRA access permission |
| Research project to be carried out by undergraduate or taught MSc / MA students *not* involving the NHS | E2D | http://www.brookes.ac.uk/Research/Research-ethics/Ethics-review-forms/ | Application reviewed and approved by FREC. Review by NRES not required |
| Service Evaluation involving past or present NHS / Social Care service users, their relatives / carers, tissue samples or information | E2D | http://www.brookes.ac.uk/Research/Research-ethics/Ethics-review-forms/ | Application reviewed and approved by DRERG. Review by NRES not required. Access permission given by R&D Department |
| An audit involving past or present NHS / Social Care users or their information | E2A (Audit) FH&LS | http://www.brookes.ac.uk/Research/Research-ethics/Ethics-review-forms/ | Application reviewed and approved by DRERG. Review by NRES not required. Access permission given by R&D Department |
| Secondary data analysis | E2S (Secondary Data analysis) FH&LS | https://www.brookes.ac.uk/Research/Research-ethics/Ethics-review-forms/ | Application reviewed and approved by DREO– Committee review not required |
| Research involving private patients | E2D or Independent Sector application form (depending on location for study) | http://www.brookes.ac.uk/Research/Research-ethics/Ethics-review-forms/ or application form used by the Private Organisation or Local Authority | Application reviewed at FREC. May require further review and approval in independent sector |

There is an expectation that the researcher will have undertaken training in research ethics and in Faculty and University processes and seek the advice of the relevant Departmental Research Ethics Officer prior to making an application to FREC or the DRERG. Where the researcher is making an application to an external REC (eg: NRES) The Faculty Research Ethics Officer rather than the Departmental Research Ethics officer should be approached for support before submission.

All applications should be made using the electronic versions of these forms; no handwritten applications will be accepted.

If you are making an application to the Departmental Research Ethics Group please send an electronic copy of your application and all supporting documentation (including all supporting documentation e.g. invitation letter, information sheet, consent form, questionnaire, gatekeeper letter, etc) to frec@brookes.ac.uk. Please address the subject heading to the relevant

Departmental Research Ethics Officer and specify your programme of study and the type of application you are making. For example: **atten: Sue_Schutz_pre-registrationMSc_nursing_E2Dform_service_eval.**

If you are making an application to the Faculty Research Ethics Committee please send an electronic copy of the application to Kellie Tune (frec@brookes.ac.uk). This should be addressed to FREC and specify your programme of study and the type of application you are making. For example: **atten: FREC_IRASform_Nursing_Staff_Project.** You should also ensure six collated, hard copies of the application form (including all supporting documentation e.g. invitation letter, information sheet, consent form, questionnaire, gatekeeper letter etc.) are delivered to Kellie Tune at Marston Road Campus before 12.00 pm on the deadline date for the Committee meeting.

All correspondence with research participants should be on Oxford Brookes University headed paper. For students, the Research Supervisor can provide this. If the research is co-sponsored e.g. by the University and an NHS organisation, guidance on the merging of letterheads can be sought from the Communications and Marketing Department.

Once the application has been reviewed and discussed at the FREC or via the DRERG, the relevant DREO/FREO will communicate the decision to the applicant within 14 days of the meeting. The project will be either 'approved', 'approved subject to amendments' or 'not approved'. If the study is 'approved subject to amendments', all amendments will be subsequently dealt with by Chair's Action. If not approved, the applicant will be invited to resubmit their application. Formal approval is notified using the form FH&LS E3 once all points of amendments have been addressed.

**Once approved, it is expected that the research will be carried out as described in the ethics application.** Any changes in protocol should be submitted to the approving FREO/DREO for approval. The duration of approval is for a period of three years.

***Approval from the FREC must be obtained BEFORE applications are forwarded to the NHS Research Ethics Service or to any other external Research Ethics Committee for review.***

## Expedited Review

In exceptional circumstances an urgent review of an application may be required. These circumstances are likely to be determined by the need to meet contractual agreements or funding body arrangements. Please see Appendix 4 for the procedure for expedited review.

# Researcher Safety

Any OBU researcher involved in fieldwork should consider their own safety when collecting data 'off site' (see http://www.brookes.ac.uk/services/hr/health_safety/docs/obuhsn31.html).

The Social Research Association also provides useful guidance on researcher safety at http://the-sra.org.uk/sra_resources/safety-code/.

### Risk Assessment

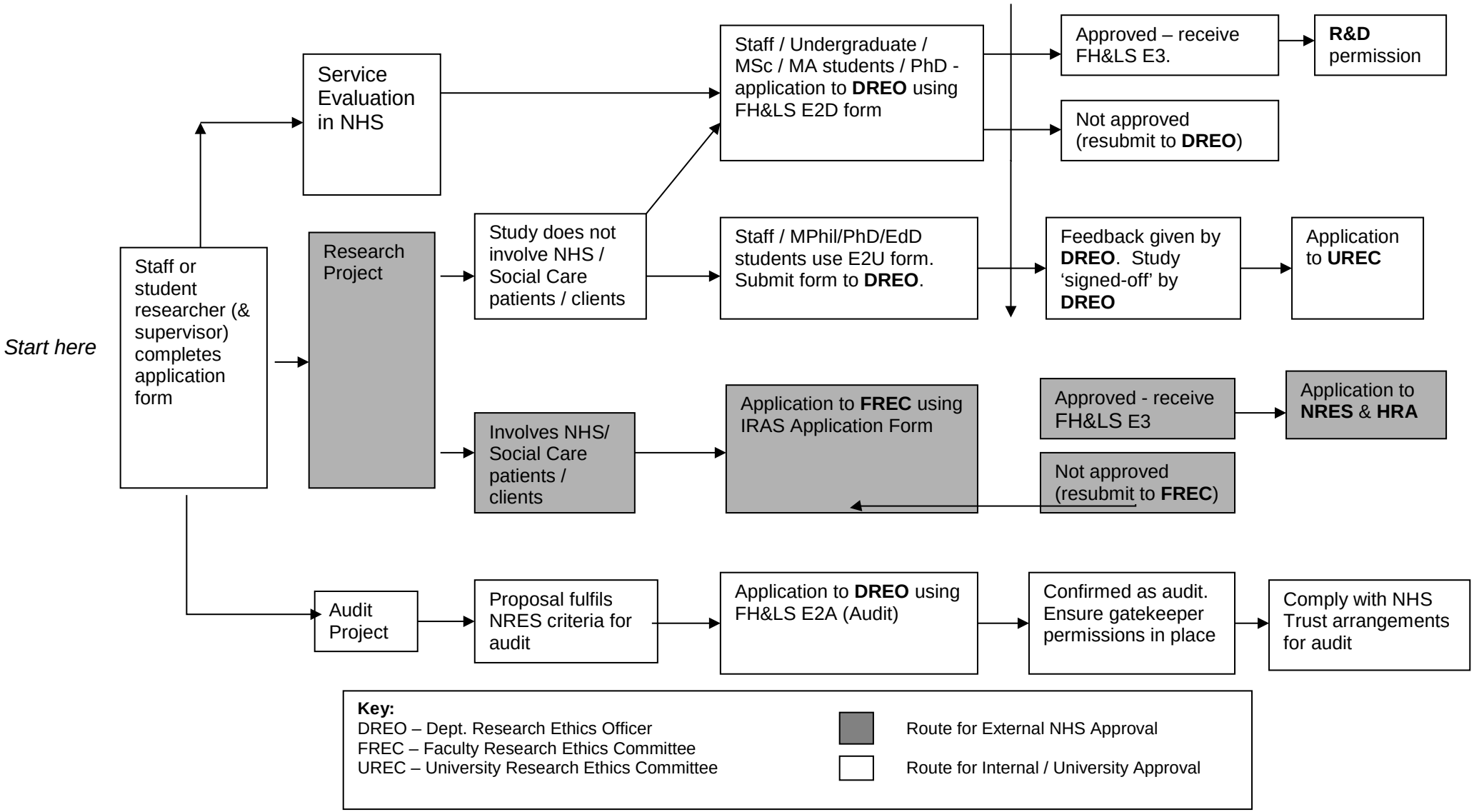
Oxford Brookes University requires that a risk assessment is undertaken prior to any work-related trips either within the UK or abroad, *including trips for the purposes of research*. Such a risk assessment must be appropriate and proportionate to the proposed research and the level of risk anticipated.

In many cases, the research itself will not pose significant risks or hazards - but this can only be established through the process of risk assessment. The purpose of risk assessment is therefore to establish the level of risk for the researcher and to the University. On this basis, the research can be planned to take all potential safety and security issues into account.

Risk assessment should be carried out in the planning phase of a project in order that additional safety measures can be put in place, as required. For guidance on how to undertake a risk assessment, see the OBU Health and Safety Notice - 36 on Risk Assessment (http://www.brookes.ac.uk/services/hr/health_safety/docs/obuhsn36.html).

The Dean of the Faculty has overall responsibility for the health and safety of those conducting research overseas. This requires an adequate assessment of the risks concerning travel, accommodation, local conditions and the research environment. Researchers themselves must also ensure that they are as prepared as is reasonably practicable. Most risks involved with research overseas are foreseeable and with careful planning can be reduced or avoided.
For further guidance on travelling and working overseas, please see OBU Health and Safety Notice 38 at http://www.brookes.ac.uk/services/hr/health_safety/docs/obuhsn38.html.

## Flowchart demonstrating the ethics review procedures for research involving human participants in the Faculty of Health and Life Sciences



# MAKING AN APPLICATION TO AN NHS RESEARCH ETHICS COMMITTEE

All applications must be approved by the FREC ***before*** a proposal can be submitted externally to an NHS Local Research Ethics Committee (LREC).

## THE NHS ETHICS REVIEW SERVICE

The purpose of the NHS National Research Ethics Service (NRES) is to 'protect the rights, safety, dignity and well-being of research participants and to facilitate and promote ethical research that is of potential benefit to participants, science and society'. It is managed via a network of Local Research Ethics Committees, each located within / appointed by a Strategic Health Authority.

Each LREC comprises professional and lay members, all of whom are volunteers. All RECs follow national guidelines for ethics review i.e. the Research Governance Framework for Health and Social Care (DoH, 2005) (see https://www.gov.uk/government/publications/research-governance-framework-for-health-and-social-care-second-edition. Ethics approval is dependent upon the research applicant satisfactorily demonstrating respect for the autonomy of research participants, concern for their welfare and the scientific validity of the project.

## THE REMIT OF NHS RESEARCH ETHICS COMMITTEES

A Local Research Ethics Committee reviews all research that involves: potential research participants recruited because of their past or present use of NHS / Social Care services, their status as relatives or carers of past or present NHS / Social care users, research that collects tissue from these users or any information that has the potential to identify them.

Audit and service evaluation do not require NHS ethics review but will require permission locally to access the field and / or data. See Appendix 5 for the NHS criteria for distinguishing between research, audit and service evaluation.

## MAKING AN APPLICATION

- All applications must be made using the IRAS application form available at www.myresearchproject.org.uk/ or the link from the Health Research Authority website at: http://www.hra.nhs.uk/research-community/applying-for-approvals/.
- The application should be completed using the question-specific guidance provided.
- This application form must be submitted to the Faculty REC for review and approval **before** submitting it to the NRES.
- After Faculty approval, a review slot must be booked either via the NRES Central Allocation Service or directly with a Research Ethics Committee. Information on how to apply is available via the Health Research Authority website.
- The application will be reviewed at the next meeting to which the applicant will be invited to attend (or should be available by phone). Further to the meeting, the Committee can seek clarification on specific issues on one occasion only.
- NRES decisions are made within 60 calendar days of the receipt of a valid application (although this varies according to the type of study reviewed). The REC decision may be communicated as part of the overall HRA approval process.
- For any queries about the application process, you can contact the NRES at iras.queries@nhs.net.

## COMPLETING THE APPLICATION FORM

### The Chief Investigator

The Chief Investigator (CI) should submit the application form for ethics approval. This is the person with overall responsibility for the design, conduct, analysis and reporting of the study. PhD / Doctoral students can be identified as the CI in their own right. In the case of other student projects (MSc / MA / Undergraduate), the Research Supervisor takes on the responsibility of Chief Investigator. In this case the **student should complete the ethics application form**, on behalf of the CI. The filter questions at the beginning of the application form should be correctly completed so the status of the study as a student project is clear.

### Documentation

The documentation submitted for LREC review should include:

- A signed and dated application form, completed using the guidance notes
- Consideration of the ethical issues involved in the project
- A full description of the way participants are identified, approached and expected to opt-in
- A full description of the way in which consent is to be sought and documented
- All data collection tools e.g. interview schedules, questionnaires, diaries, data collection forms
- All correspondence with participants i.e. poster advertisements, participant invitation letter, participant information sheet, consent form, privacy notice – in plain English and non-technical language. This should be signed (where appropriate) and dated, on appropriate letterhead, include the study title, NRES study number and version number
- A research protocol including supporting reference material
- The Curriculum Vitae of the applicant(s)
- Details of scientific peer review. The REC will expect to see evidence of the scientific peer review of the application by the Host organisation. The FREC reviews the science of the study to address this requirement. On approval, an E4 scientific peer review for will be issued that should be enclosed with the application to the LREC.
- A letter confirming who will act as the Sponsor for the research. Oxford Brookes University will act as the Research Sponsor for all research conducted by staff and students. Kellie Tune, Research Ethics Lead, will issue a letter to this effect and should be named as the Sponsor's contact with the main REC.
- The arrangements for indemnity insurance.

### Site-Specific Assessment

Studies that involve only low risk research procedures, including research involving qualitative methods only, are exempt from Site-Specific Assessment (SSA). Clinical research and studies involving adults unable to consent for themselves *do* require SSA.

### Health Research Authority (HRA) approval / R&D site access permission

Once ethics approval has been obtained, permission is also required to conduct a study at the research site. If the project is research and involves NHS patients / their carers / data, then HRA approval is required before the research can begin. The only exception to this is if the project is being carried out for an educational purpose and data collection will take place at only ONE site. In this event, only local R&D permission is required from the single research site. When an application is submitted for NHS research ethics review, this will trigger the HRA approval process.

If the project is an audit, service evaluation or only involves NHS staff or premises i.e. no NHS patients, R&D management approval is required at the research site before data collection can begin. OBU has a local arrangement with OUHT in that they will process the Faculty application form for the purposes of providing access permission. Following Faculty ethics approval, Kellie Tune will provide the necessary documentation for including with the application for R&D access approval. However, R&D Departments very in the information required to permit access to an

NHS site, and whilst Appendix 7 contains that normally requested in Oxfordshire, you should establish this by contacting the R&D Department directly for study sites outside of Oxfordshire.

**Research Passports**

A number of checks must be undertaken on a researcher before they are permitted to conduct research in the NHS. This process can be lengthy, especially as the same checks are carried out at each site before a research project can begin. In order to increase efficiency of this process, Research Passports have been introduced. A form is completed by the researcher, verified by their employer and then validated by an NHS organisation. The result is a 'Research Passport' that can be presented to each NHS organisation for which R&D management approval is sought. See: https://www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm for further information. Hilary Currie (hjcurrie@brookes.ac.uk) deals with all student applications for research passports.

**Proportionate Review**

A system for the proportionate scrutiny of applications raising no material ethical issues has been established. In this case, a sub-Committee of the main REC reviews the application with a view to issuing an opinion within 14 days.

A 'No Material Ethical Issues Tool' should be used to determine whether a study is suitable for proportionate review. This and a useful Proportionate Review Frequently Asked Questions Factsheet can be downloaded at: http://www.hra.nhs.uk/resources/applying-to-recs/nhs-rec-proportionate-review-service/.

To book an application for proportionate review, applicants should contact the Central Booking System. Telephone: 0207 104 8000. This line is open 9.00 to 16.30pm Monday- Friday Alternatively the PR booking team can be contacted by email at nres.cbs@nhs.

## OXFORDSHIRE RESEARCH ETHICS COMMITTEES

There are three RECs in Oxfordshire all located within South Central Strategic Health Authority. For meeting dates please contact the administrator (contact details below) or see the NRES web-site http://www.hra.nhs.uk/news/rec/ .

**Oxfordshire Research Ethics Committee A**

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| Chair: Dr Hugh Davies |
| REC Manager: Natasha Bridgeman |
| Tel: +44207 1048045 |
| E-mail: nrescommittee.southcentral-oxforda@nhs.net |

**Oxfordshire Research Ethics Committee B**

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| Chair: Mr Chris Foy |
| REC Manager: Vicky Canfield-Duthie |
| Tel: +44207 1048058 |
| E-mail: nrescommittee.southcentral-oxfordb@nhs.net |

**Oxfordshire Research Ethics Committee C**

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|---|
| Chair: Professor Nigel Wellman |
| REC Manager: Charlotte Ferris |
| Tel: +44207 1048049 |
| E-mail: nrescommittee.southcentral-oxfordc@nhs.net |

**Postal address for committees A, B & C**

South West REC Centre
Level 3, Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

# SOCIAL CARE RESEARCH

The Social Care Research Ethics Committee is part of the NRES. It is appointed by the Social Care Institute for Excellence (SCIE) and reviews applications involving the social care sector i.e. local authority, private and voluntary settings.

- Social care research funded by the Department of Health
- Social care research involving adults lacking capacity and required under the Mental Capacity Act (2005)
- Social care research involving sites in England and another UK country
- 'Own account' research undertaken by Councils with Social Services responsibilities, where research team consider there are significant ethical issues
- Studies where the investigators do not have access to other review mechanisms e.g. University Research Ethics Committees
- Studies taking place within the NHS using social science or qualitative methods, but where the research does not involve clinical interventions or changes to clinical care
- Intergenerational studies involving both adults and children or families are research participants

For further guidance, please see the Standard Operating Procedures for Research Ethics Committees Version 6.1 (NRES, 2015), annex K.

# RESEARCH VERSUS AUDIT

The distinction between research and audit can be blurred. The NHS National Research Ethics Service (NRES) only reviews research projects involving patients, their carers or data.

The NRES *does not* review projects for audit or service evaluation, although the former must comply with data protection legislation and local NHS Trust arrangements for the conduct of audit. The NRES criteria for categorising research, audit and service evaluation are contained in Appendix 5.

Staff and students embarking on research or audit projects need to be able to distinguish one from the other to ensure that the correct approvals are obtained prior to the commencement of data. Research is a systematic investigation that aims to generate new knowledge whereas clinical audit has been defined as "a quality improvement process that seeks to improve patient care and outcomes through systematic review of care *against explicit criteria* and the implementation of change" (National Institute for Clinical Excellence, 2002).

The following table provides a useful distinction between the two activities.

**The Differences between Research and Audit**

| RESEARCH | CLINICAL AUDIT |
|---|---|
| ● A systematic investigation which aims to generate new knowledge – may be qualitative or quantitative in approach<br>● DEFINES best practice/standards | ● A systematic peer review of healthcare in order to monitor or improve services<br>● MONITORS current practice against best practice/known standards |
| ● May involve an experimental approach (e.g. randomly allocating patients to different treatment groups) | ● Never involves an experimental approach (e.g. will never involve allocating patients to different treatment groups)<br>● May involve giving patients different treatments but these alternatives will all be accepted as normal practice, and patients would normally be allowed to choose |
| ● May involve a new treatment | ● Never involves a new treatment |
| ● May involve extra disturbance to patients over and above normal clinical management. This may take the form of specially arranged interviews, focus groups, interventions, clinical assessments or postal communications | ● May involve asking people about their satisfaction with care or health state following specific treatment, but not much else |
| ● Usually involves well-defined, often strict selection criteria for participants recruited | ● Recruitment criteria not usually as well defined or strict |
| ● Generalisable/transferable; hopes to inform/influence care across the NHS and beyond | ● Not generalisable; hopes to influence the care given by local health services |
| ● Intention to publish/widely disseminate outputs | ● Primarily local dissemination, principally to service providers; outputs may be published where it will assist other audit |
| ● Often commissioned/funded externally by those from outside the local service (e.g. Medical Research Council, Department of Health, Pharmaceutical Company) | ● Funded by local health services |
| ● Often conducted by those outside of the local service e.g. Universities) | ● Usually conducted by those providing the service locally |

From: How to conduct a clinical audit
Reproduced with permission from the Clinical Effectiveness Team, CGSU, ORHT
Please also refer to: http://www.hra-decisiontools.org.uk/research/docs/definingresearchtable_oct2017-1.pdf

If in any doubt as to whether a project should be categorised as research or as audit, please consult the DREO or seek clarification from the Research and Development Office within the relevant NHS Trust.

## Conducting an audit

In the first instance, information should be sought from the local NHS Trust to establish whether they have a policy for the approval of audit projects and corresponding guidelines for conducting an audit. Such information would be available from the Clinical Effectiveness Team or the Clinical Governance Support Unit.

In Oxfordshire, all audit projects should be registered with the Clinical Effectiveness Team and such details are maintained on the Trust's Datix Clinical Audit Database.

## The ethical dimensions of audit

Generally, the main ethical issue with audit is the protection and use of patient information. All audit projects must comply with the Data Protection Act (2018), the recommendations of the Caldicott Committee (1997) and the NHS Confidentiality Code of Practice (2003). All of these documents can be viewed at www.doh.gov.uk.

The main points that should be noted are that:

- Data should be used only for the purposes for which it has been collected
- Patients must be fully informed about the uses to which information about them may be put
- Clinicians are **not** entitled to access patient records for either audit or research purposes without the appropriate permission
- Any researcher requiring access to patient records must seek permission from either the NRES or the Local NHS Trust (usually via the Clinical Effectiveness Team)

# MAKING AN APPLICATION TO THE UNIVERSITY RESEARCH ETHICS COMMITTEE (UREC)

Any research to be carried out by *staff* or *research students* (MPhil/PhD/EdD) must be forwarded to the University Research Ethics Committee (UREC) for approval. The only exception to this is where the project involves NHS patients their carers or their data. In this case, the project needs to be approved by the Faculty REC and then forwarded to a Local Research Ethics Committee (LREC) for approval by the National Research Ethics Service instead - see page 9).

In the first instance, an E2U application form should be completed, which is accessible via the University research ethics web site http://www.brookes.ac.uk/Research/Research-ethics/Ethics-review-forms/ .

This form should then be forwarded to the relevant Departmental Research Ethics Officer (DREO) three weeks before the UREC meeting for feedback and 'signing-off'. Once approved by the DREO, the application can be forwarded to the University Committee for review.

Applications are reviewed and then discussed at the Committee meeting.

A 'light touch' procedure is also in place for those projects raising no material ethical issues. See http://www.brookes.ac.uk/Research/Research-ethics/Determining-light-touch-review/. The FREO can advise on whether a study fits the criteria for 'light touch' review.

The membership of UREC comprises all the Faculty Research Ethics Officers, lay representatives and the University Information Compliance Officer.

The Committee meets five times per semester usually in weeks 0, 3, 6, 9 and 12 and twice during the vacation period. One complete hard copy of the application, signed by the relevant Faculty Research Ethics Officer, should be send to Louise Wood, the University Research Ethics Committee Administrator (ethics@brookes.ac.uk / 01865 484445), two weeks before the meeting date.

The dates for the University Research Ethics Committee meetings for the academic year 2018 / 2019 are listed in Appendix 2.

# DATA MANAGEMENT

## DATA MANAGEMENT AND INFORMATION SECURITY

Research data must be kept securely at all times. All data needs to be stored in accordance with the Data Protection Act (2018) and Oxford Brookes Policy for Academic Integrity. Data should also be accessible for monitoring and audit purposes, and participants need to be made aware of how their data will be used and accessed.

Laptops and other devices should be password protected and / or encrypted. Data may be stored in Google Drive, for which the University has a security agreement. Personal / identifiable information should be kept in a Trial Master File separate from research data. Please refer to the guidance on file encryption: https://www.brookes.ac.uk/research/Research-ethics/Resources/Encrypting-files/

There is further information about research data management available on the University research support pages: https://www.brookes.ac.uk/research/research-support/data-management/.

## DATA PROTECTION

The University expects all staff and students to be responsible for the security of information. Every person handling information or using University information systems is expected to observe the information security policies and procedures, both during and, where appropriate, after his or her time at the University. There is more information about data security, information management, IT policies, procedures and regulations at: https://www.brookes.ac.uk/it/information-management/.

# INSURANCE FOR OXFORD BROOKES UNIVERSITY RESEARCHERS

The University has public liability insurance that provides third party cover for loss and damage for which the University is legally responsible, with a few exceptions e.g. wilful damage. This policy covers claims made against staff, students and all participants in research projects, regardless of whether the research takes place on University property.

No cover for personal injuries/damages is held by the University but it does have personal accident cover that provides death and disability benefits.

A standard indemnity form has been produced by the University to be used by staff and students visiting external organisations to carry out research work. The normal situation is that the organisation will have insurance against its own legal liability towards visitors by virtue of a public liability policy.

Occasionally staff may be asked to produce proof of insurance cover to external persons. In addition, staff may wish to print proof of covers for their own use. Staff needing to print such documentation can do so from the link **https://intranet.brookes.ac.uk/fls-intranet/finance/policies-and-procedures/insurance/**. However, copies of insurance certificates for clinical trials must be requested directly from the University Insurance Officer (see below).

The University Insurance Policy applies to all staff and students registered for a programme of study at Oxford Brookes. This includes students undertaking research work overseas.

## CLINICAL TRIALS

Insurance cover for clinical trials requires special arrangements because such research is considered to be 'high risk' by the University Insurers.

A clinical trial is defined as 'an investigation or series of investigations conducted by any person for a medicinal purpose'. A medicinal purpose shall mean:

- Treating or preventing disease
- Diagnosing disease or ascertaining the existence, degree or extent of a physiological condition
- Assisting with or altering in any way the process of conception or investigating or participating in methods of contraception
- Inducing anaesthesia
- Otherwise preventing or interfering with the normal operation of a physiological function

Cover for clinical trials will be automatic in many cases e.g. if the trial is within the UK and is based solely upon questionnaires, venepuncture, measurements of physiological processes or collections of body secretions by non-invasive methods, or the administration by mouth of foods or nutrients or variation of diet other than the administration of drugs or other food supplements.

However, the University insurance policy excludes the following:

- Trials outside the United Kingdom
- Trials involving more than 100 participants
- Trials involving the use of drugs or surgery
- Trials requiring no-fault cover
- Research subjects known to be pregnant at the time of the trial
- Research subjects under 5 years of age

- Clinical trials in which the medicinal purpose is:

(a) assisting with, or altering, the process of conception
(b) investigating, or participation in, methods of contraception

- Clinical trials involving genetic engineering (other than trials in which the medicinal purpose is treating, preventing and diagnosing disease)
- Trials where the substance under investigation has been designed and manufactured by the University

In the event of the above, specific insurance cover needs to be negotiated by the Insurance & Risk Officer before the trial takes place. The Faculty Research Ethics Officer must refer all clinical trials involving the above exclusion list to the University Insurance Office. Researchers will be asked to complete the Clinical Trial Questionnaire (see Appendix 6).

Please note that, in addition to the above,

- All relevant clinical trials must be conducted in accordance with the Medicines (Application for Grants of Product Licenses) (Products for Human Use) Regulations 1993 and the Medicines (Standard Provision for Licences and Certificates) Amendment (No. 2) Regulations 1992
- The University shall obtain the Association of the British Pharmaceutical Industry recommended indemnity or equivalent where a clinical trial is sponsored by a pharmaceutical manufacturer or similar organisation

Gary Lambourne is the University Insurance Officer and he may be contacted on 01865-483498. For further information about insurance, see https://intranet.brookes.ac.uk/fls-intranet/finance/policies-and-procedures/insurance/ .

# CORRESPONDENCE WITH RESEARCH PARTICIPANTS

All correspondence should be on Oxford Brookes headed paper. For student research, it is the responsibility of the Research Supervisor to ensure that headed paper is used. If the research is being co-sponsored by another agency e.g. OUH NHS Trust or a commercial company, both organisations / logos can be included on the correspondence. Guidance on the positioning such logos can be obtained from the Marketing Department.

***Please note:***
***If the study involves NHS patients / carers you MUST follow the HRA guidance on the required format for participant information sheets and consent forms. See: http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-and-participant-information/,***
***This should be read in conjunction with https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/transparency-wording-public-sector/ for compliance with GDPR* / Data Protection Act (2018).**

The following information may be helpful when compiling / designing correspondence with participants:

**Invitation Letter**
It is good practice to send potential research participants an invitation letter. An invitation letter should include:

- who you are (i.e. a student / member of staff at Oxford Brookes University)
- how you have obtained access to them as potential research participants and why you are writing to them (i.e. you are inviting them to take part in a research study because they …)
- an invitation to read the accompanying information sheet containing more detailed information about the study
- a statement that says there is no obligation to take part. However, if invitees do wish to opt in to the research, you need to explain how they do this
- a 'thank you' for reading the letter/information sheet
- the signature of the Research Supervisor, if you are undertaking the research as a student
- It can be useful to provide a brief summary of what is involved in the research including (eg: questionnaire / interview) and any estimated time-burden.

**Participant Information Sheet**
A participant information sheet contains the finer details about a proposed investigation. Potential recruits to the research study must be given sufficient information to allow them to decide whether or not they want to take part.

An information sheet should be written in simple, non-technical terms and be easily understood by a lay-person. A question and answer format should be used, as per the University template (see http://www.brookes.ac.uk/Research/Research-ethics/Guidelines-for-informed-consent/). In order to facilitate ease of reading, use a minimum font size of 12 points. It is preferable to use the word "would" rather than "will" throughout. Will implies consent has already been given and could be considered coercive, whereas "would" implies a decision has yet to be made.

Version numbers and dates should be included at the bottom of the protocol, invitation letters, information sheets and consent forms. This should be updated each time the documents are revised.

**Consent Form**

Clear evidence that the participant has given informed consent to take part in the study must be obtained. Consent must be unambiguous must involve a clear affirmative action or opt-in by the research participant. This will usually be in the form of a signed consent form although other evidence may be acceptable. Where the researcher is using a signed consent from participants should usually be invited to initial (not tick) to indicate their informed consent.

Where interviews are the method of data collection, a clause should be added to the consent form seeking permission to use anonymous quotes in the presentation of research findings and agreement to the tape/video-record the interview. Where the researcher is undertaking an anonymous survey participants need to demonstrate they opt in, therefore the first questions on the questionnaire can confirm consent with yes/no tick boxes.

The University template for a consent form is available at:
http://www.brookes.ac.uk/Research/Research-ethics/Guidelines-for-informed-consent/.

**GDPR compliant privacy notice**

If you are undertaking research within the NHS you will need to adhere to the standard transparency wording for Public Sector Sponsors in your participant information sheet. You can access the standard phrases here: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/transparency-wording-public-sector/.

The University has developed a GDPR-compliant privacy notice template for researchers. All research where there is a risk of identifying individual participants will need to provide a privacy notice to all participants. The Privacy notices must set out how personal information is used and what the data subjects' (research participants) rights are. Furthermore your participant information sheet will need to provide details about how data is processed, stored and managed, and what participants' rights are in relation to their data.

For further information the researcher is advised to seek the advice of the IT Services Information Management team info.sec@brookes.ac.uk or 01865 485420, https://www.brookes.ac.uk/Research/Research-ethics/Review/Guidelines-for-informed-consent/. You can download a privacy notice here: https://www.brookes.ac.uk/research/research-ethics/forms-and-templates/.

# COMMONLY RAISED QUESTIONS ABOUT THE ETHICS APPROVAL PROCESS

The following questions represent those commonly asked about the ethics approval procedure.

***I am a member of staff within the FH&LS and currently registered on a Masters programme at the University. Do I seek ethics approval for the research project I am undertaking for my dissertation in my capacity as a member of staff or as a student?***

*Ethics approval is required in your capacity as an MSc student. In the first instance, approval for the study must be sought from the DREO. If the study involves NHS patients, staff or premises, the application will need to be reviewed by the FREC before it is forwarded to an NHS Research Ethics Committee for approval. If the study does not involve NHS patients, staff or premises, approval only at Departmental level is required.*

***I am employed as a nurse/midwife/physiotherapist in the NHS. I have recently sought and obtained ethical approval from the NRES for a research study I am intending to carry out relevant to my work. However, I have also subsequently registered on an MSc degree programme at Oxford Brookes University and intend to conduct this research for my dissertation. What should I do about Faculty research ethics approval and who will indemnify me for this project?***

*If you submitted the original application to the NRES in the capacity of Chief Investigator, the FREC requires that you forward a complete copy of the REC application and the approval letter to the Chair of the Committee. Details of the study will be entered onto the Faculty Research Ethics Committee database and you will be deemed to have complied with the Faculty Ethics Approval Procedure.*

*If your research is a small component of a larger study and you **did not** make the original NRES application yourself, you need to complete Form E2D. This requires you to consider the ethical dimensions of the research you are proposing to undertake. This form should be forwarded to the DREO, together with relevant all correspondence with research participants and a copy of the REC approval letter for the entire project. The application will not be reviewed at a Committee meeting unless the Chair of the Committee has any concerns about either the ethics or the science of the study. Having done this, you will have complied with the Faculty requirements for ethics approval. Indemnity insurance will be provided either by your employer or the University, depending on who is identified as the Sponsor for the research.*

***I am unclear whether my intended study is research or audit. Should I seek ethics approval for my work?***

*In the first instance, discuss this with both your Research Supervisor and your Manager in the place where you work. Seek guidance from the Clinical Effectiveness Team if required. Consult your DREO if clarification still required. If the project is considered to be audit, complete FH&LS form E2 (Audit) and forward it to the DREO.*

***I wish to conduct a study that is relevant to my job as a nurse manager. This would require me to collect data within my place of work. Are there ethical difficulties with this?***

*Conducting research within the place where you work does potentially raise ethical difficulties.*

- ***Role Conflict***

*A researcher has to ensure that the roles of researcher and clinician are clearly separated. Information that is gathered for the purposes of providing clinical care cannot be used as research data. Likewise, data gathered as part of the research process may have implications for clinical care – but the researcher is bound by a duty of confidentiality to the research participant. This has to be balanced against the clinician's Code of Professional Conduct/duty of care that can, on occasion, over-ride the duty of confidentiality. Similar dilemmas exist where researchers are also work colleagues. As part of their employment contract, they may be required to report incidents and or actions taken by others. This has the potential to compromise the researcher / work colleague relationship.*

- **Recruitment**

*The potential exists for coercion in recruitment. If potential participants are work colleagues, they may feel obliged to participate because they depend upon the researcher for a good working relationship. If there is a very small population, there may be pressure on participants to opt in, and participants may be identifiable. Furthermore, if you have managerial responsibility for potential participants, they may feel that their work performance would be negatively appraised by declining to participate or even that their promotion opportunities could be compromised by refusal to take part. Patients/clients are similarly in a vulnerable position if they are dependent upon the researcher for their health care.*

- ***Data Collection***

*If the research participant knows the researcher, openness and truth telling may be compromised during data collection thus compromising the validity of the data. The participant may provide information that they believe the researcher wishes to hear!*

- ***Data Analysis***

*The researcher's inside knowledge about the workplace has the potential to influence the interpretation of the data.*

*Steps to address/minimise these issues should be taken in the design phase of a study.*

**Appendix 1**

# FACULTY OF HEALTH AND LIFE SCIENCES RESEARCH ETHICS COMMITTEE

# TERMS OF REFERENCE

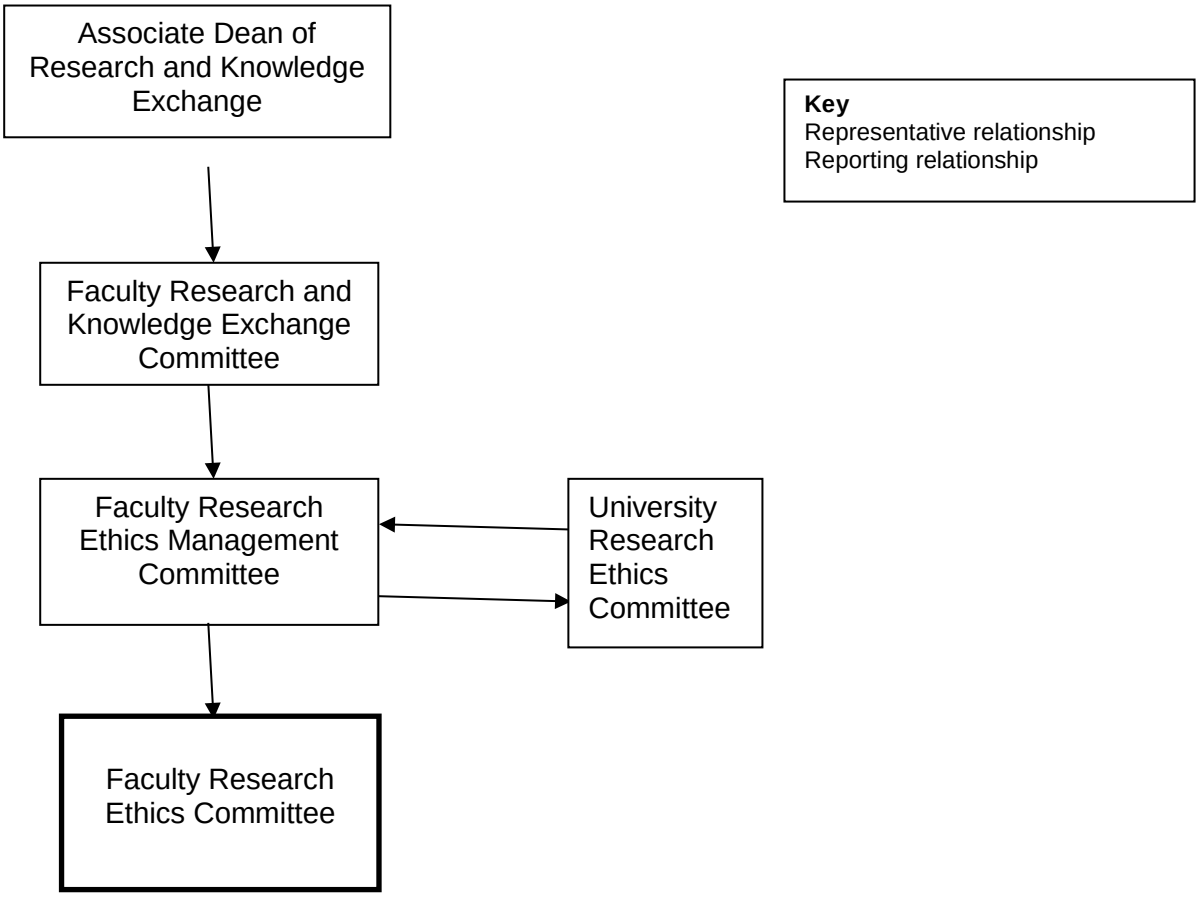
**Purpose**
To review and approve research to be undertaken in the NHS by staff and students from the Faculty of Health and Life Sciences

**Terms of Reference**
- To establish, implement and review ethics procedures and guidelines for research projects involving the NHS and to disseminate these throughout the Faculty
- To ensure that the procedures for ethics review within the Faculty of Health and Life Sciences reflect the principles of the Research Governance Framework for Health and Social Care (DoH, 2005) and enable researchers to meet these requirements
- To review and approve research involving human participants or human data to be carried out in the NHS by staff and students from the Faculty of Health and Life Sciences
- To carry out an independent peer review of the scientific dimensions of the research to meet National Research Ethics Service requirements
- To provide informational support, advice and guidance to staff and students on conducting research involving human participants / human data in the NHS

**Modus Operandi**
1. Meetings will be monthly throughout the calendar year, except during August. Additional meetings may be convened to manage the capacity of work during 'busy' periods or in extraordinary circumstances
2. A maximum of 8 applications will be reviewed and discussed at any one meeting
3. The Chair of the Committee, or nominated Committee member in the Chair's absence, will undertake all correspondence with applicants and sign all Approval Forms (Form E3) on behalf of the Committee
4. In the unusual event that an expedited review is required, the Research Ethics Lead or the nominated Deputy, on behalf of the Committee, will undertake this
5. Outstanding issues arising from a proposal that has been reviewed at a Committee meeting will subsequently be dealt with by Chair's Action
6. Committee decisions will be notified to applicants within 10 working days of the Committee meeting

**Membership**
- Departmental Research Ethics Officers (To Chair meeting)
- Representatives from the School of Nursing and Midwifery, Department of Sport, Health Sciences and Social Work, Department of Biological and Medical Sciences, Department of Sport, Health Sciences and Social Work, Department of Psychology, Health and Professional Development
- In the event that discipline-specific expertise is required, other members of the Faculty will be co-opted onto the Committee
- Members of the Committee should be knowledgeable about research, have an interest in research ethics and normally hold a Master's degree
- The Committee will be quorate with 5 members present, one of who must be the Chair (or nominated representative in the Chair's absence)

**Organisational Relationships**



# UNIVERSITY RESEARCH *ETHICS* COMMITTEE MEETING DATES

## 2018 / 2019

| UREC Meeting date | Application deadline to REO | Application deadline to Louise Wood |
|---|---|---|
| **Semester One 2018** | | |
| Wednesday 26 September 2018 (week 0) | 5 September | 12 September |
| Wednesday 10 October 2018 (week 3) | 19 September | 26 September |
| Tuesday 30 October 2018 (week 6) | 10 October | 17 October |
| Wednesday 21 November 2018 (week 9) | 31 October | 7 November |
| Tuesday 11 December 2018 (week 12) | | |
| | | |
| **Semester Two 2019** | | |
| Wednesday 23 January 2019 (week 0) | 2 January | 9 January |
| Thursday 14 February 2019 (week 3) | 24 January | 31 January |
| Wednesday 6 March 2019 (week 6) | 13 February | 20 February |
| Thursday 28 March 2019 (week 9) | 7 March | 14 March |
| | | |
| **Vacation** | | |
| Wednesday 6 June 2018 | 16 May | 23 May |
| Wednesday 11 July 2018 | 20 June | 27 June |

Applications should be submitted to the relevant Departmental Research Ethics Officer for feedback and 'signing off' **three weeks before** the UREC deadline. After this, one complete copy of the application should be submitted to Louise Wood, **two weeks before** the UREC deadline.

Contact for further information: Louise Wood, UREC Administrator

ethics@brookes.ac.uk or 01865-484445

**Appendix 3**

# FACULTY OF HEALTH AND LIFE SCIENCES RESEARCH ETHICS COMMITTEE MEETING DATES

## 2018 / 2019

| REC deadline date | REC meeting date |
|---|---|
| **Semester One 2018** | |
| Monday 10 September 2018 | Tuesday 18 September 2018 – week 0 |
| Monday 8 October 2018 | Tuesday 16 October 2018 – week 4 |
| Monday 5 November 2018 | Tuesday 13 November 2018 – week 8 |
| Monday 10 December 2018 | Tuesday 18 December 2018 – week 13 |
| | |
| ***Semester Two 2019*** | |
| *Monday 7 January 2019* | *Tuesday 15 January 2019 – week -1* |
| *Monday 11 February 2019* | *Tuesday 19 February 2019 – week 4* |
| *Monday 4 March 2019* | *Tuesday 12 March 2019 - week 7* |
| *Wednesday 25 March 2019* | *Tuesday 2 April 2019 - week 10* |
| *Monday 29 April May 2019* | *Tuesday 7 May 2019 - week 13* |
| *Monday 3 June 2019* | *Tuesday 11 June 2019* |
| *Monday 8 July 2019* | *Tuesday 16 July 2019* |
| *No meeting in August* | *No meeting in August* |
| | |
| ***Semester One 2019*** | |
| *Monday 17 September 2019* | *Tuesday 18 September 2018 – week 0* |

Six collated, hard copies of the application form (including all supporting documentation/correspondence) should be delivered to Kellie Tune at Marston Road Campus before 12.00 pm on the deadline date for the Committee meeting for review at the next Committee meeting.

**One electronic copy** should also be forwarded to Kellie Tune, Chair of the FREC (frec@brookes.ac.uk).

**Appendix 4**

# PROCEDURE FOR EXPEDITED ETHICS REVIEW

**Expedited review**
It is recognised that there may be some exceptional circumstances where an urgent review of an ethics application is required, outside of the normal Faculty ethics review mechanism. These circumstances are likely to be determined by the need to meet contractual agreements with funding bodies.

**Criteria:**

- 'Exceptional circumstances' refer to unusual situations where the time frame for the study precludes the normal internal ethics review process. Evidence of such time constraints will be required
- The expedited review process will consider only the ethical dimensions of the proposed study. An independent scientific review of the research must therefore accompany the application
- The applicant must be an experienced researcher (this does not apply to student research or student researchers)
- The applicant must have previous experience of making a submission to a Research Ethics Committee

**Process:**

- An approach should be made to the Chair of the Faculty Research Ethics Committee requesting an expedited review
- If the Chair agrees to the request and the above criteria are met, the DREO, or nominated deputy*, will undertake an expedited review of the study on behalf of the Committee
- Where the DREO, or nominated deputy, is able to 'sign off' the application on behalf of the Faculty, the necessary paperwork will be provided (E3 form, insurance form and Research Sponsor letter)
- If the DREO considers the application raises significant ethical issues that need resolution prior to submission to a NHS Research Ethics Committee, the application will either be discussed with another DREO or referred to the Faculty Ethics Committee for review
- Any decisions made via the expedited review process will be reported to the Faculty Research Ethics Committee at the next meeting
- The outcome of applications submitted to external Ethics Committees via this route will be monitored

* 'Nominated deputy' refers to a member of the Research Ethics Committee

**Appendix 5**

# NRES CRITERIA FOR RESEARCH, AUDIT AND SERVICE EVALUATION

This table was developed by the HRA (October, 2017) and is reproduced from the guidance for researchers and reviewers on the HRA web site: http://www.hra-decisiontools.org.uk/research/docs/definingresearchtable_oct2017-1.pdf

| RESEARCH | SERVICE EVALUATION | CLINICAL/ NON-FINANCIAL AUDIT |
|---|---|---|
| The attempt to derive generalisable or transferable new knowledge to answer questions with scientifically sound methods* including studies that aim to generate hypotheses as well as studies that aim to test them, in addition to simply descriptive studies. | Designed and conducted solely to define or judge current care. | Designed and conducted to produce information to inform delivery of best care. |
| Quantitative research – can be designed to test a hypothesis as in a randomised controlled trial or can simply be descriptive as in a postal survey.<br><br>Qualitative research – can be used to generate a hypothesis, usually identifies/explores themes. | Designed to answer: "What standard does this service achieve?" | Designed to answer: "Does this service reach a predetermined standard?" |
| Quantitative research - addresses clearly defined questions, aims and objectives.<br><br>Qualitative research – usually has clear aims and objectives but may not establish the exact questions to be asked until research is underway. | Measures current service without reference to a standard. | Measures against a standard. |
| Quantitative research – may involve evaluating or comparing interventions, particularly new ones. However, some quantitative research such as descriptive surveys, do not involve interventions.<br><br>Qualitative research – seeks to understand better the perceptions and reasoning of people. | Involves an intervention in use only. The choice of treatment, care or services is that of the care professional and patient/service user according to guidance, professional standards and/or patient/ service user preference. | Involves an intervention in use only. The choice of treatment, care or services is that of the care professional and patient/service user according to guidance, professional standards and/or patient/service user preference. |
| Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care. May involve data collected from interviews, focus groups and/or observation. | Usually involves analysis of existing data but may also include administration of interview(s) or questionnaire(s). | Usually involves analysis of existing data but may include administration of simple interview or questionnaire. |
| Quantitative research – study design may involve allocating patients/ service users/healthy volunteers to an intervention. Qualitative research – does not usually involve allocating participants to an intervention. | No allocation to intervention: the care professional and patient/ service user have chosen intervention before service evaluation. | No allocation to intervention: the care professional and patient/service user have chosen intervention before audit. |

| | | |
|---|---|---|
| May involve randomisation. | No randomisation. | No randomisation. |
| Normally requires REC review but not always. Refer to http://hra-decisiontools.org.uk/ethics/ for more Information. | Does not require REC review. | Does not require REC review. |

**Please note:** Although clinical audit and service evaluation do not require NRES review, these projects **will require R&D permission** (see Appendix 7) and may raise ethical issues.

**Appendix 6**

# CLINICAL TRIALS QUESTIONNAIRE

(FOR INSTITUTION SPONSORED TRIALS ONLY)

*If the Trial is within the UK and refers to the following there is no need to complete this Questionnaire:*

***Trials solely based upon questionnaires, venepuncture, measurements of physiological processes or collections of body secretions by non-invasive methods, or the administration by mouth of foods or nutrients or variation of diet other than the administration of drugs or other food supplements***

Institution (sponsor):

Title of Trial

Number of research subjects (participants)

1 Advise details of the Trial and attach copy of the Protocol submission to the Ethics Committee

2 Is the Trial to be held in UK?
If "No" please provide full detail

3 Who will be involved in conducting the Trial?

If medical practitioners are involved, will they be covered by the MDU or other organisation?

4 Does the Trial involve use of drugs or surgery?

5 Are any of the research subjects known to be pregnant?

6 Are any of the research subjects under 5 years of age?

7 Is the purpose of the Trial :
a) investigating or participating in the methods of contraception
b) assisting with or altering the process of conception?

8 Does the Trial involve genetic engineering?

9 Will the Trial use a pharmaceutical product designed or manufactured by the Institution?

10 Proposed commencement date AND period of the Trial

**If any of the answers to 4 – 9 are "Yes" please provide full details**

**ON NO ACCOUNT MUST THE PROJECT COMMENCE UNTIL INSURANCE APPROVAL IS GIVEN**

**Signed** **Dated**

PRINT NAME: SCHOOL: EXTN:

**Definitions:**
**Clinical Trial means** an investigation or series of investigations conducted on any person for a Medicinal Purpose

**Medicinal Purpose means** treating or preventing disease, diagnosing disease or ascertaining the existence degree of or extent of a physiological condition, assisting with or altering in any way the process of conception or investigating or participating in methods of contraception inducing anaesthesia otherwise preventing or interfering with the normal operation of a physiological function.

**Appendix 7**

# SEEKING R&D PERMISSION IN OXFORDSHIRE

Your project is not considered research as described by GAfREC, then you may still require HRA approval before the research can begin. The exception to this is if the project is being carried out for an educational purpose and data collection will take place at only ONE site, and you are not seeking NIHR Clinical Research Network support. In this event, only local R&D permission is required from the single research site.

If the project is an audit, service evaluation or only involves NHS staff or premises i.e. no NHS patients, R&D management approval is required at the research site before data collection can begin. OBU has a local arrangement with OUHT in that they will process the Faculty application form (E2D) for the purposes of providing access permission.

Please be aware R&D Departments vary in the information they require in order to provide access to a research locality. By way of an example, the following list is provided by Oxford Health NHS Trust. When applying for R&D permission please contact the relevant Department directly to ascertain the information they require. Please refer to http://www.hra.nhs.uk/resources/before-you-apply/is-nhs-rec-review-required/ and http://www.hra.nhs.uk/about-the-hra/our-plans-and-projects/assessment-approval/student-studies-led-england/ for further information.

## Documents required for research studies wishing to gain Oxford Health NHS FT NHS Permission (management approval)

**For low risk studies involving OHFT staff only**

- Application to University/Faculty Ethics Committee (signed)
- University /Faculty Ethics Committee Approval (signed)
- Proposal/Protocol (Version controlled)
- Signed & dated CV (all researchers involved in the study including supervisors)
- Participant Information (version controlled)** i.e. Participant Information Sheet, Invitation Letter; Participant Consent(s); Other Participant-related Documentation, e.g. letter to GP, Advert)
- Relevant permissions from internal management to contact and recruit their members of staff

**Notes**

NHS permission is required when researchers are conducting research on any of the following: NHS premises, staff or patients – their tissue, organs or data.

* OHFT employees and those with honorary clinical contracts of employment with the Trust may apply for OHFT sponsorship for their research study if it involves the consenting of participants and NHS ethical approval. This is separate to the indemnity provided for usual clinical responsibilities.

** Studies sponsored by OHFT will need OHFT logo. If the study is sponsored either commercially or by an academic institution, the sponsor may or may not require the presence of their logo on participant-related documentation at each participating NHS site. OHFT as a PIC – the Trust will not require local participant-facing documents or submission of an SSI form.

*** Right of access via Letter of Access – contact R&D department for advice and details.

**Appendix 8**

# USEFUL RESOURCES

The Caldicott Committee: Report on the review of patient-identifiable information - December 1997, NHS Executive. Available at www.doh.gov.uk

Data Protection Act (2018) London, The Stationary Office. Available at https://www.gov.uk/government/collections/data-protection-act-2018

Department of Health (1996) Health Service Guideline: The Protection and Use of Patient Information, HMSO. Also available at www.doh.gov.uk

Department of Health (2005) Research Governance Framework for Health and Social Care, 2nd edition, London, The Stationary Office.

Guide to the General Data Protection Regulation (2018) London, The Stationary Office. Available at: Available at https://www.gov.uk/government/publications/guide-to-the-general-data-protection-regulation.

Economic and Social Research Council (2016) Research Ethics Framework, ESRC. Available at: www.esrc.ac.uk/researchethics

Medical Research Council (2002) Personal Information in Medical Research, MRC
Also available at www.mrc.ac.uk

National Ethics Advisory Committee (NEAC) (2003) Ethical review of observational research, audit and related activities. Available at www.neac.health.govt.nz

National Institute for Clinical Excellence (2002) Principles for Best Practice in Clinical Audit, NICE. Available at www.nice.org.uk

National Patient Safety Agency (2007) Guidance for applicants to the National Research Ethics Service, London, NPSA

National Patient Safety Agency (2007) Defining research, London, NPSA

National Patient Safety Agency (2007) Explaining research, London NPSA

Smith R (1992) Audit and research. *British Medical Journal*, 305: 905. Available at www.bmj.com