

Terms of Reference: Research Ethics Committee (REC)

Date of approval:	March 2012 (UCO REC), June 2012 (Academic Council), July 2017 (RSSC), November 2017 (Academic Council)
Last Reviewed:	November 2017
Date for Review:	November 2018
Version Number:	V3.0
Chair:	External and Lay Member
Secretary:	Research and CAE Officer

Context

In recent years research governance requirements have increased across the health care sector. However much of the research carried out into osteopathic practice and its related fields falls outside of the Governance arrangements for NHS Research Ethics Committees (GfREC). This is because these types of studies tend to deal with patients and practitioners who largely operate in the private sector.

The UCO adheres to standards of good practice identified in the Osteopathic Research Governance Framework produced by the National Council of Osteopathic Research. This framework was informed by existing national policy and adapted to the context of the osteopathic profession.

We aim to deliver high quality research from the faculty, in collaboration with other institutions and with stakeholder partners. The UCO also provides research related learning experiences to undergraduate and postgraduate students. The UCO strives to produce work to high academic and ethical standards in all areas of practice. As part of this process all proposed research work undergoes ethical consideration whether it involves participants within the institution or outside the institution; this currently includes students and staff from the UCO and applications from students from other institutions who would like to carry out work with our faculty, students or patients. The same criteria apply to funded or postgraduate research. We also review proposals from external institutions planning to research osteopathic practice outside of the institution.

The current process and committee was constituted in 2005. Processes and procedures are reviewed and amended annually.

Terms of Reference

To be responsible to Academic Council to:

1. Protect and safeguard the welfare of patients, students and staff as research participants.
2. Examine and review undergraduate, postgraduate and other research proposals regarding ethical suitability to be undertaken under the auspices of the institution and related contexts.
3. Keep up-to-date with research ethics and the broader research environment, developing and amending strategy and policy for research proposal approval.
4. Report any concerns regarding patterns of issues to the Research and Scholarship Strategy Committee and Academic Council.
5. Provide ethical advice for researchers as required or requested.
6. Produce an annual report.

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Rolling agenda items

1. To examine undergraduate, postgraduate and other research proposals regarding ethical suitability to be undertaken under the auspices of the institution and in related osteopathic contexts.
2. To manage, keep under review (including efficiency and effectiveness) the research ethics process.
3. To keep up-to-date with research ethics and the broader research environment, developing and amending strategy and policy for research proposal approval.
4. To produce an Annual Research Ethics Report for the RSSC, including action plans for the coming year.
5. To review the REC Terms of Reference.
6. To review Research Ethics Guidance Form.

Procedures

Screening

Hard copy and electronic copy is submitted to the Secretary. Two or more members of the screening team provide initial review to identify applications that do not require full review by the committee or require submission to an NHS Research Ethics Committee. The external representative on the screening committee will review a selection of applications and consider applications where there is disagreement amongst the screeners.

Criteria for exclusion from review by the full Research Ethics Committee are as follows:

1. Audit or service evaluation as described in the National Research Ethics Service Guidance.
2. Literature based study.

Proportionate review

Applicants carrying out audit or service evaluation studies and literature based studies will be required to sign and submit a Statement of Ethical Compliance, in which they commit to abiding by Department of Health (2005) [Research governance framework for health and social care](#). This must be co-signed by the applicant's supervisor. The form will be sent out to all students who do not submit an ethics application.

Full review

Applications are sent to all members of the committee. All members of the committee are asked to examine the proposals submitted, but one member is nominated to present it to the meeting.

Written comments are provided to the Secretary at the meeting. Additional comments and the conclusions of the committee are summarised and returned to the applicants with a decision.

The committee makes one of the following recommendations for student led research:

- a) Unconditional approval.
- b) Conditional approval with recommendations. The research cannot proceed unless these have been addressed and amendments scrutinised ("Approved with minor amendments to be completed by the Student", "Approved with minor amendments to be authorised by the

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Supervisor”, “Approved with amendments to be approved by the Supervisor and subcommittee of REC”).

- c) Reject the proposal, with reasons with the expectation of a resubmission (UCO, “Not approved – Resubmit to the UCO REC”)

The committee makes one of the following recommendations for non-student led research:

- a) Unconditional approval.
- b) Conditional approval with recommendations. The research cannot proceed unless these have been addressed and amendments scrutinised (“Approved with minor amendments to be completed by the principal investigator”, “Approved with amendments to be approved by the Supervisor and subcommittee of REC”).
- c) Reject the proposal, with reasons with the expectation of a resubmission (, “Not approved – Resubmit to the UCO REC”)

The Secretary is the official line of communication between the applicants and the Committee.

Ad-hoc applications are sent out for comments to members of the committee. These are collated by the Secretary and Chair and fed back to applicants along with a decision.

Researchers will be expected to undertake their research as described in their application and to sign a written agreement to this effect. For students registered for study with the UCO, failure to comply may lead to disciplinary action by the UCO.

- Post approval changes

Appendix 1 contains indicative items and responses to requests and deviations from the approved application. This will be circulated to applicants with their letters of approval.

Use of subcommittee

Currently subcommittees are created on an ad hoc basis and can be used with two of the responses that the REC can give to applications.

- Approved with amendments to be checked by supervisor and subcommittee of REC
 - Subcommittees will be used when there are issues of utility due to marked limitations that would benefit from review by experts in the particular methodology.
 - Completion of the amendments to be checked by the supervisor and an appropriate sub-committee with a final check by REC secretary.
- Not approved. Resubmit to the REC.
 - Subcommittees will be used when there are issues of utility due to limitations and marked limitations that would benefit from review by experts in the particular methodology.
 - Completion of the amendments to be checked by an appropriate sub-committee that makes a recommendation to the Chair. The Chair makes the final decision on the response.

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Expedited Review

Expedited review will be considered on a case-by-case basis.

Review of submissions accepted for expedited review may be conducted at meetings or by email.

Acceptable reasons for expedited review include timing, funding, personal circumstances and institutional problems.

Requests for expedited reviews should be made using the Expedited Review Request Form in which reasons for the request are provided and justified. This should be accompanied with a cover email

Conflicts of interests

Conflicts of interest may only be raised by committee members. Conflicts of interest will be noted in minutes of meetings.

Types of conflict of interest:

- 1) Committee member has a conflict of interest with regards their own students' projects.
 - Conflicted REC member formally declares their conflict of interest to REC.
 - Conflicted REC member withdraws from review of this project.
- 2) Committee member has a conflict of interest with regards their own research projects.
 - Conflicted REC member formally declares their conflict of interest to REC.
 - Conflicted REC member withdraws from review of this project.
 - As the committee includes other UCO staff, who could benefit at an institutional level, the committee makes a recommendation for the outcome and the Chair makes final decision.
- 3) Committee member has a conflict of interest with regards a project by an external applicant with whom the member has a working relationship.
 - Conflict noted.
 - Conflicted REC member withdraws from review of this project.
- 4) Committee member has a conflict of interest with regards the intellectual content of a project.
 - Conflicted REC member formally declares their conflict of interest to REC.
 - Conflicted REC member withdraws from review of this project.
- 5) Committee member has a conflict of interest not covered by points 3.1-3.4
 - Conflicted REC member formally declares their conflict of interest to REC.
 - Conflicted REC member withdraws from review of this project.

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Appeals

An applicant may appeal a decision of the REC. In the first instance the concerns raised should be discussed with the Secretary who may discuss these with the Chair. Where resolution through discussion cannot be arrived at applicants may a formal appeal. There are two different forms of appeal:

1. If an undergraduate applicant is dissatisfied with the outcome of the application, i.e. with the professional judgment of the committee, they must submit written grounds for an appeal to the REC Secretary. The application will reviewed again by the full committee together with the written grounds of the appeal. The applicant and supporting supervisor will be invited to attend the REC meeting.
- 2.1 If an undergraduate applicant, applicant is dissatisfied with the outcome of the application and believes correct procedures were not followed, they must submit written grounds for an appeal to REC Secretary. The application will reviewed again by the full committee together with the written grounds of the appeal. The applicant and supporting supervisor will be invited to attend the REC meeting.
- 2.2 If a post-graduate applicant is dissatisfied with the outcome of the application and believes correct procedures were not followed, they may submit their application and written grounds for an appeal to the Institute for Health Research Ethics Committee (IHREC) at the University of Bedfordshire (<http://www.beds.ac.uk/research-2/ihr/ethics>). The decision of the IHREC will be final.

Frequency of meetings

The Committee usually meets three to five times a year.

Composition and conditions of membership

- Research representative, Head of Research
- Research representative, Vice Principal (Research)
- Postgraduate Studies representative
- Research Officer (REC Secretary)
- Head Librarian
- Clinic representatives
- External representatives
- Lay members (not currently registered as osteopaths)
- Undergraduate Research Officer/ Critical Analysis and Enquiry Unit Leader

Members are recommended to the Chair for invitation from Faculty and elsewhere. The term of service for each member is rolling.

The Chair may seek review and discussion of applications electronically and by mail if applications are made outside of the usual meeting cycle.

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Quorum

Meetings will be quorate provided the Chair (or alternate Chair) and four other members are present, of which one should be a lay member.

Reporting and subcommittees

Reports to:

The Research Ethics Committee reports directly to the Research and Scholarship Strategy Committee (RSSC) through submission of minutes of its meetings. It submits an Annual Report to the RSSC, for final approval by the Academic Council.

The Research Ethics Committee reports, as necessary, any concerns regarding patterns of issues to the RSSC and Academic Council.

Receives reports from:

The Ethics Screening Committee is a subcommittee of the Research Ethics Committee. It reports annually to the Research Ethics Committee by a summary of actions.

AGREED