National Council for

NCOR

Osteopathic Research

A Short Guide to the Research Governance Framework for Practising Osteopaths

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Introduction

This is a brief guide to the Research Governance Framework (RGF), 2005. A copy of the full NCOR RGF can be obtained online at www.ncor.org.uk or from the Research Officer.

It is intended for all practising osteopaths wanting to undertake research within their own practice. There are many aspects of the framework that apply to the osteopathic colleges that are not presented here; the colleges are recommended to consult the full document.

What is Research Governance?

Research governance can be described as the broadly agreed framework of regulations, principles and standards of good practice that exist to achieve and continuously improve research quality across all aspects of health care in the United Kingdom and worldwide.

Why do we need a Research Governance Framework?

Research Governance is needed to:

- Provide a clear framework within which to conduct research
- Promote good practice in research
- Monitor practise and performance
- Enhance scientific and ethical quality
- Minimise risk in research
- Safeguard participants in research
- Protect researchers and investigators by providing clear guidelines for the conduct of research

What does the Research Governance Framework include?

The research governance framework includes:

- Key principles to be considered when conducting research of high quality.
- Ethical issues and the considerations that must be taken into account when conducting research in an ethical manner.
- Responsibilities of individuals involved with the research process.
- Information concerning the manner in which data is gathered and the need for adequate protection of sensitive patient data to comply with current legislation.
- Advice on how to avoid misconduct in research and procedures for dealing with such activity.
- Appendices giving details of sources of additional information which may be helpful to researchers with diverse areas of experience.

What do I do if I'm proposing to conduct some research?

It would be helpful for you to consult the Research Governance Framework for Osteopathy. If you have any further questions once you have read this, please speak to the Research Officer for further information.

What is the difference between research, audit and evaluation?

- **Research** is about creating new knowledge; knowledge about whether new treatments work and whether certain treatments work better than others. Research forms the basis of nationally agreed professional clinical guidelines and standards – it determines what best practice is. Research can encompass a variety of approaches, both qualitative and quantitative and each approach adds valuable information about patients and their experience of osteopathic treatment. Research should not necessarily be seen to be composed of large scale trials which could only be run in certain environments with extensive funding. A great deal of valuable information can be gleaned from small scale observational studies e.g. case reports and pieces of qualitative research which are suitable for private practitioners to undertake.

- **Audit** of practice may be a numerical audit to obtain a profile of patient throughput, characteristics or outcomes or a comparison of practice against a defined standard e.g. are we following professional guidelines? Are we following best practice as agreed by the wider healthcare arena? Audit can be a useful way to identify research priorities.

- **Evaluation** is frequently commissioned. It assesses the effectiveness of practice(s) within a particular health care setting. Evaluation reports are written so that action can be taken in the same setting, and such reports are intended to influence the work of the evaluator and/or their team. Evaluation tends to inform practice development and may be also be discussed with a wider audience.

If I'm conducting an audit and evaluation, do I need to have the approval of a Research Ethics Committee?

Audit and evaluation do not require the approval of an ethics and governance committee.

If I'm conducting Research, what do I do and where do I go?

Research involving human participants requires the opinion and approval of a Research Ethics Committee. If you are considering conducting research, it would be helpful for you to consult the Research Governance Framework for Osteopathy initially. This will provide guidance for many of the areas you will need to consider before you start the research process.

What if I'm conducting research with patients referred to me via an NHS general practitioner or consultant?

If you are an osteopath working in the NHS or working with NHS patients referred directly by a general practitioner or consultant, you will need to

apply to your local research ethics committee (NHSREC). Details concerning your local NHSREC can be found through the Council for Research Ethics Committees (COREC). An application form will have to be completed; this is available on the COREC website www.corec.org.uk.

What do I do if I'm working collaboratively with practice-based osteopaths?

Osteopaths working in private practice can apply for an opinion and approval to their local NHSREC. Discussions are being held concerning the possibility of establishing an NCOR Research Ethics Committee; this is designed for osteopaths conducting research who are not part of the NHS or attached to a higher education institute. However, existing REC committees are often overburdened with medical and pharmaceutical applications and are known to refuse to give an opinion concerning osteopathic research.

If a refusal of this type happens following the establishment of an NCOR Research Ethics Committee, you will be able to contact the NCOR Research Ethics Committee (NCOR REC). This can be achieved by speaking to the Research Officer, Carol Fawkes (c.a.fawkes@brighton.ac.uk). If you intend to contact the NCOR REC, it would be helpful to consult the Research Governance Framework beforehand. This can be found on the NCOR website www.ncor.org.uk. The Research Ethics Committee will only look at your application if all elements of your form are complete.

What do I do if I'm collaborating with researchers and staff in the NHS or working with NHS patients and staff?

You will need to contact your local NHS Research Ethics Committee. This information can be found by discussing the research with your local NHS Trust Research and Development department and the local Trust Research Governance Officer.

What do I do if I'm working with multiple collaborations in multiple settings?

An application will need to be made to COREC for permission by a Multi Centre Research Ethics Committee (MREC). Further information will be found at www.corec.org.uk.

What do I do if I'm working in higher education as a research student as part of an MSc, MRes or collaborating with the staff of a higher education institute?

Guidance on the ethical requirements will vary between higher education institutions (HEIs). Some will have their own Research Ethics Committees (URECs); others will require application through the local NHSREC depending on who is involved in the project. Smaller HEIs will have smaller "in house" ethics committees.

How long will the Research Ethics Committee take?

The proposed NCOR REC is projected to meet approximately 4 times per year. Hence, it will take a maximum of three months from when your application is made to receive an opinion.

Will there be a cost implication?

No costs will be charged to the applicant.

Who sits on the Research Ethics Committee?

The committee will be chaired by an independent Chair who is experienced in ethics and quality review procedures. There will also be representatives present who are experienced in quantitative and qualitative approaches. Individuals who are experienced in ethics committee work will also be present as will lay members of the public.

Will I have to attend the Research Ethics Committee?

In certain circumstances you may be required to attend the committee meeting to provide clarification about your research proposal.

How long would I be required to attend for?

No longer than half an hour.

Are there standard forms available to be completed?

Yes. These can be obtained from Carol Fawkes (c.a.fawkes@brighton.ac.uk).
The forms can also be found on the NCOR website www.ncor.org.uk.

What do I do if I need more information?

Please consult the Research Governance Framework for Osteopathy initially; it is available on the NCOR website www.ncor.org.uk. If you have further questions when you have consulted that, please contact the Research Officer, Carol Fawkes (c.a.fawkes@brighton.ac.uk).

What are my responsibilities as a researcher?

All practising osteopaths are responsible for the care of their patients who may be involved in research within their practice.
Osteopaths must satisfy themselves that the planned research is

- valid
- is likely to be beneficial to patients' future care
- has been the subject of approval by a research ethics committee, peer reviewers and any other appropriate scrutinising authorities within their organisation.

What are the responsibilities of my research supervisor in Higher Education?

An academic supervisor must ensure that:

- The academic institutions fulfil their responsibilities as a research sponsor.
- Research projects are of scientific quality and clinical relevance through an adequate level of protocol review.
- The student has adequate academic supervision and support to conduct the study successfully. Evidence for this would be provided by the provision of a contract between the supervisor and the student and a record of supervisory meetings.
- The student has the competencies expected to conduct the study successfully and to ensure that the provision of student training as required in research methods, use of equipment and other competencies required for the completion of the project.
- The student is aware of and complies with the research governance framework and is aware of scientific misconduct procedures, student handbooks and research guidelines of the osteopathic educational institution.
- The project is compliant with all current health and safety legislation, data protection legislation, and other relevant legislation including data storage.
- If any exploitable intellectual property arising from the research is identified, the NHS consortium and/or other organisation concerned e.g. an OEI or other academic institution is notified.
- The project is submitted for ethics approval by the NHS REC system, social care organisation system, osteopathic educational institution's committee or NCOR research ethics committee system (as appropriate).
- Any financial impact on the NHS/osteopathic education institution or other relevant organisation is agreed and approved by all the parties involved.
- For each project all sections of the student agreement pro forma are completed fully and the pro forma is signed by the academic supervisor, clinical/work based supervisor and the student. Upon completion of the study the pro forma should be submitted to the nominated university/academic officer. The pro forma for a student project can be found in Appendix 13 and the pro forma for a group project can be found in Appendix 14 of the NCOR Research Governance Framework.
- Provide assistance in any investigation arising from any complaint received in respect of actions taken by the student as part of the research activity.

If you want to apply for Research Ethics approval, please read the full NCOR Research Governance Framework document (available at www.ncor.org.uk) before completing your application form.