

Ethics and Osteopathic Research

Many practitioners when coming to research for the first time are unclear about the place ethics holds in the research process and the value it contributes. The requirement for ethical safeguards can be traced back to historical events.

The end of World War II revealed atrocities that had taken place within the concentration camps in Europe. A variety of medical experiments had been carried out on detainees producing great suffering and stress and contributing little or nothing of value to the body of medical knowledge. When the full extent of the activities in these camps was fully revealed, the 23 physicians and scientists involved were brought to trial in Nuremberg in 1946/7. This group of individuals were charged with crimes against humanity. On completion of the trial, the medical trial judges defined the essential obligations of researchers in the medical field to human research subjects and this is enshrined in the Nuremberg code.

Medical ethics in the twentieth century has taken its guidance from the Declaration of Helsinki. The Declaration of Helsinki is the most important international ethical guideline on biomedical research involving human subjects. It was first published in 1964 and most recently updated (and accepted) in 1996. It examines the involvement of patients in research, not just volunteers, and addresses issues surrounding individuals who are viewed to be 'incompetent' to make informed judgements e.g. by age or state of physical or mental health. A complete version of the Declaration of Helsinki can be found at <http://www3.imperial.ac.uk/pls/portallive/docs/1/49857.PDF>

Principles of Ethical Research:

When conducting research, it is important to be aware of four basic principles that need to be considered at all times:

- **Beneficence:**
Research must be suitably designed to provide the greatest potential benefit to research subjects.
- **Non-maleficence:**
Research must be appropriately designed to ensure that the risk of harm to a research subject is minimised.
- **Autonomy:**
Research subjects must be able to freely choose to become involved in a research study. Undue pressure or other coercive activities are never acceptable. The use of inducements for participation in research, whether among patients or fellow professionals, must be at the discretion of each individual osteopathic educational institution. However, this aspect of policy and practise should be clear at the beginning of a research project.
- **Justice**
Justice can be described in terms of fairness. In research this can be compared to fairness in terms of the potential risks weighted against the

potential benefits of an intervention and fairness of access to the resulting proposed benefits of such an intervention for example.

Conducting Ethical Research:

The Department of Health, the largest organisation concerned with UK health care, requires that all research involving patients, service users, care professionals or volunteers (or their organs, tissue or data) is reviewed independently to ensure it meets ethical standards. The osteopathic profession needs to conduct research with an awareness of similar standards of practise.

Informed Consent:

Informed consent is at the heart of all ethical research. All studies must have appropriate arrangements for obtaining patients'/subjects' consent and the ethics review process must pay particular attention to those arrangements.

Summary of Information Required for Informed Consent:

In order for research participants to give informed consent, they must be aware of, and have sufficient time to consider, the following explanations summarised here:

- The purpose of the research.
- The procedures (what would happen to potential participants should they agree to take part and what would happen should they decline to take part).
- The risks (physical, psychological, social or other).
- The potential benefits (or absence of them) to the individual, to others or to society.
- A statement that individuals may decline to participate without any detrimental effect on their situation (for example, care, treatment, education).
- A statement that, should they agree to participate, they may withdraw freely at any time without giving a reason and without any consent given and to require that her/his own data be destroyed.
- The information that, in some circumstances, it may not be possible to identify data as having come from an individual (for example, data from focus groups) and, therefore, that it may not be possible to destroy such data.
- The arrangements to be made for the secure storage and eventual disposal of the study data may be retained on the hard disc of a computer even after they have been deleted.
- An assurance of anonymity and/or confidentiality, including any limits to confidentiality.

- Contact details of the principal researcher(s).
- Contact details of any research ethics committee that has reviewed and approved the research.
- Advice of potential participants' right to report any procedures that seem to compromise their welfare and details of the appropriate authority to which such concerns may be reported.

Further information can be found at:

www.dh.gov.uk/assetRoot/04/01/91/86/04019186.pdf

Research Ethics Structures in the United Kingdom

A researcher wishing to conduct research in the United Kingdom is required to obtain an ethical opinion, particularly if the research is intended for publication. The organisation that deals with this process in the United Kingdom is the Central Office for Research Ethics Committees (COREC). When examining a particular area of practice it is important first of all to decide whether that examination of practice should correctly be described as research, audit or evaluation.

Defining Research, Audit and Evaluation.

Research is concerned with many things including the creation of new knowledge; investigating whether new treatments work and if certain interventions are more effective than others. Research forms the basis of nationally agreed professional clinical guidelines and standards – it determines what best practice is.

Audit of practice is a means of obtaining a profile of patient throughput, characteristics or outcomes. It can also be a means to discover if we are following professional guidelines. Are we following best practice as agreed by the wider healthcare arena?

Similarities between audit and research:

- Audit and research involve answering a specific question regarding the quality and appropriateness of treatment(s) for patients.
- Audit and research can be carried out either on patients to be recruited in the future (prospectively) or patients who have already experienced treatment (retrospectively).
- Audit and research involve careful sampling, questionnaire design and analysis of findings.
- Both activities should be professionally led.

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 also be discussed with a wider audience.

A decision making flowchart to assess whether you are undertaking research or audit is shown below:

Decision Making Flowchart to assess whether Research or Audit is being carried out.

RESEARCH	AUDIT
May involve experiments based on a hypothesis.	Never involves experiments and involves measuring against pre-existing standards.
It is a systematic investigation.	It is a systematic review of practice
It may involve random allocation.	It never involves random allocation.
There may be extra disturbance to patients.	There is little disturbance to patients.
It could be a new treatment.	It never involves a completely new treatment.
Creates new knowledge about effectiveness of treatment approaches	Answers the question “are we following best practice?”
May involve experiments on patients.	Patients continue to experience their normal treatment management.
It is usually a lengthy process and involving large numbers of patients.	It is usually carried out involving a small number of patients and in a short time span.
It is based on a scientifically valid sample size (except in the case of some pilot studies).	It is more likely to be conducted on a pragmatically based sample size.
Extensive statistical analysis of data is routine. Data analysis can take a number of forms depending on whether qualitative or quantitative research has been carried out.	Some statistics may be useful.
Results can be generalisable and hence publishable. Quantitative research tends to be more easily generalisable than qualitative work.	Results are only relevant within local practice settings (although the audit process may be of interest to a wider audience and hence audits are publishable).
Responsibility to act on findings is unclear.	Responsibility to act on findings rests with individual osteopaths.
Findings influence the activities of clinical practice as a whole.	Findings influence activities of practitioners within a practice.
Always requires ethical approval.	Does not require ethical approval
Research can identify areas for audit.	Audit can be a precursor to clinical research by pinpointing where research evidence is lacking.

Insurance and Research:

An element of risk may be involved for subjects participating in research. The extent of this anticipated risk must be made clear to the subjects and the relevant research ethics committee. Insurance requirements to cover research should be clear; arrangements for dealing with adverse events and compensation in the event of non-negligent harm must also be clearly explained to participants. As a practising osteopath, it is a courtesy to write to your insurer enclosing a copy of your protocol and details of how an ethical opinion has been sought. Research involving a new intervention or extreme risk should also have the explicit consent of the insurer.

Responsibilities Relating to Research Ethics Committees (RECs)

- i. Research should not proceed without prior opinion and approval of a research ethics committee (REC) as described above. Academic or research organisations usually have their own research ethics committees with clearly defined terms of reference. Further information on RECs can be found at www.corec.org.uk.

Research Ethics Committees are not Responsible for

- i. Giving an opinion on the quality and appropriateness of the research methodology proposed by a researcher. However, RECs expect research proposals to have received appropriate scrutiny prior to submission to address weaknesses in research methodology and statistics chosen by a researcher.
- ii. Providing legal advice; nor are they liable for any of their decisions in this respect.
- iii. It is the responsibility of the researcher (and the NHS, if appropriate) not to break the law, irrespective of the decision of a REC.
- iv. Ensuring that a research study follows the agreed protocol and monitoring its progress: this responsibility remains with the principal investigator, the sponsor and the researching organisation.

Which Ethical Structures are Appropriate?

Osteopaths practising in the NHS should apply for ethical approval from COREC. Osteopaths working in an accredited college or university should apply to their university REC (UREC) or observe REC arrangements made by their osteopathic educational institution, but should be aware that they may require REC approval from an NHS research ethics committee.

Osteopaths working in private practice should consult their local NHS REC to seek their opinion, or that of an osteopathic REC (based within an osteopathic educational institution).

The requirements for determining whether a research project is ethical or not can be found in great detail in: Emanuel EJ, Wendler D, Grady C. *Journal of the American Medical Association*, 2000; 283 (20): 2703 (<http://jama.ama-assn.org>).

The steps to be considered for osteopaths in private practice and working in the NHS when seeking ethics approval can be found in Figures 1 and 2 respectively.

Ethics Decision Making Tree for Osteopaths in Private Practice.

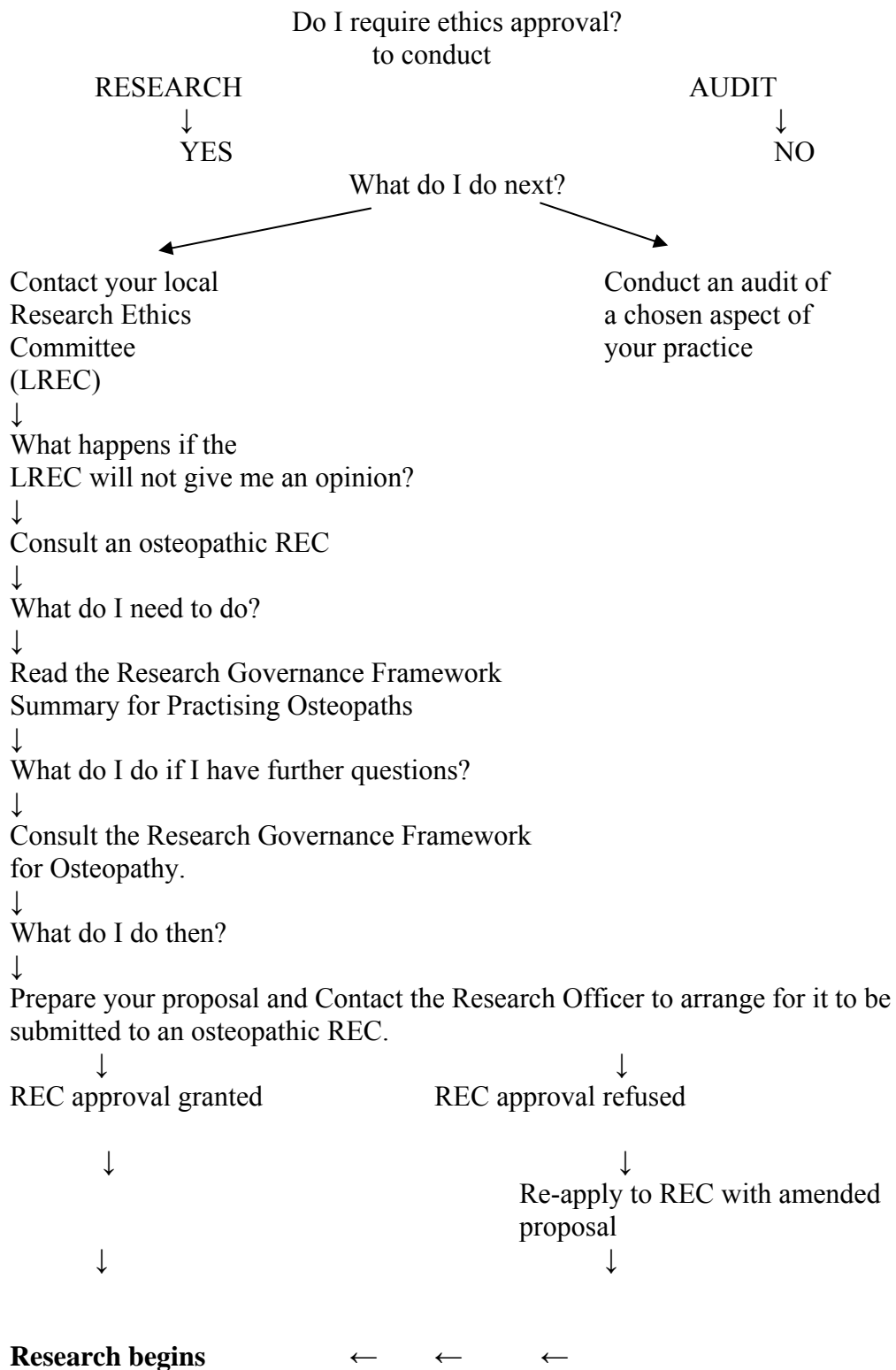
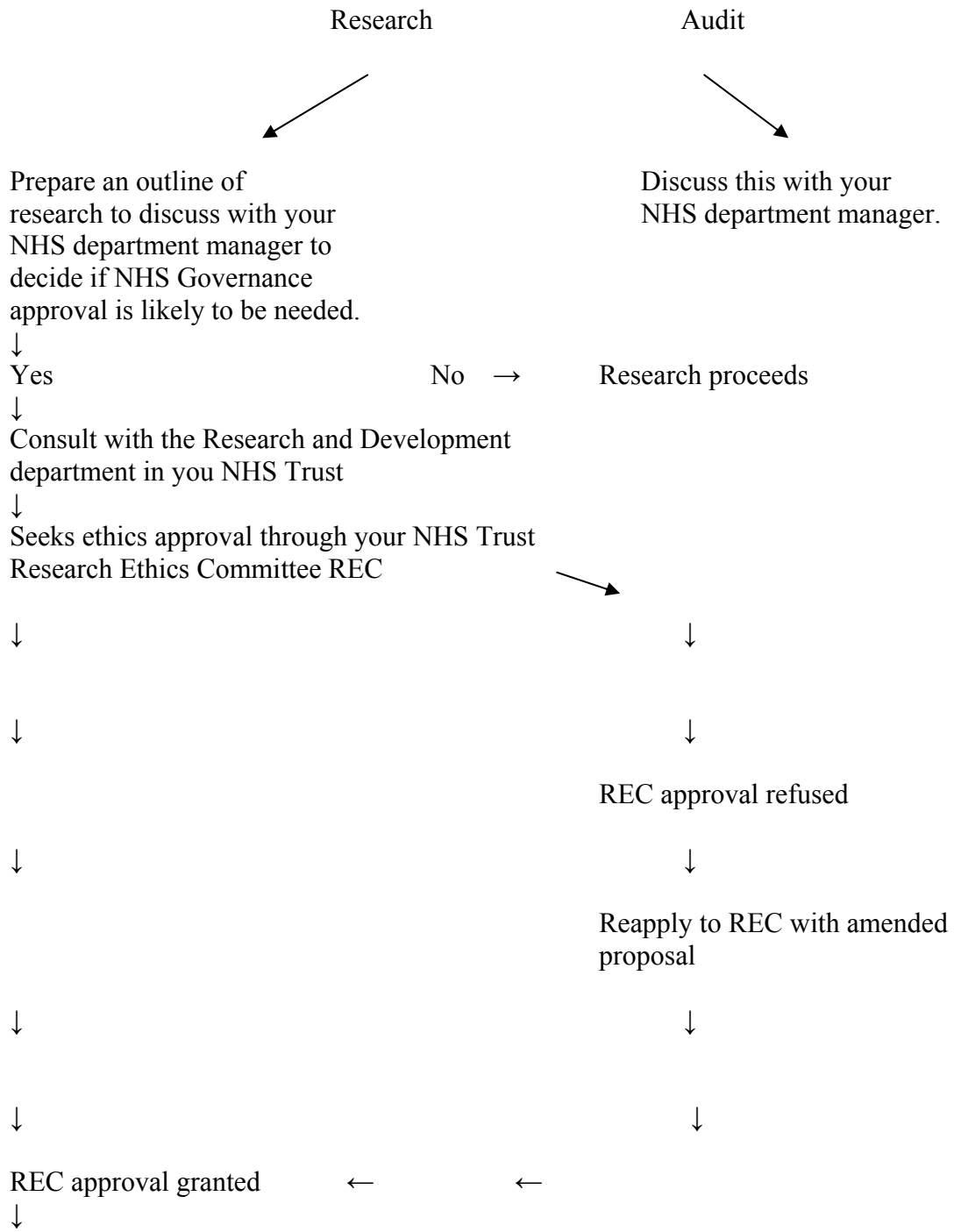


Figure 1

Ethics Decision Making Tree for Osteopaths Working in the NHS.

What do I need to do if I want to conduct:



Confirmation of approval from NHS R & D and Research begins.

If you are working in private practice and thinking of conducting some research and need any guidance on the ethics process, please contact NCOR by emailing c.a.fawkes@brighton.ac.uk

Figure 2