National Council for Osteopathic Research

RESEARCH GOVERNANCE FRAMEWORK for OSTEOPATHS

Executive Summary

The Research Governance Framework for Osteopathy is intended to demonstrate best practice in osteopathic research. A number of key areas will be covered in the main body of the document and additional information will be provided in the appendices. The document covers the following areas:

- 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 levels of experience.

- Ethical issues and the considerations that must be taken into account when conducting research in an ethical manner.

- Key principles to be considered when conducting research of high quality. (See Appendix 1).

Table of Contents

Table of Figures

Introduction

Research is vital to the successful promotion of health and well being within the nation. Many of the key advances in the last century have depended on research. Health care professionals and the public they care for are increasingly looking to research for facilitating improvements in practice. Applied research can underpin the development of new ways of promoting and protecting health. Other health care professions and Higher Education Institutions (HEIs) have had Research Governance and Ethics Frameworks for some time. Increased association is occurring now between osteopaths and the NHS; osteopaths have lacked a Research Governance Framework and this document is an attempt to address the situation.

Osteopathic research is in its infancy. The National Council for Osteopathic Research (NCOR) was formed in October, 2003; it has been created to support the development of osteopathic research nationally. It is important for researchers, clinicians, patients and participants in research that safeguards are put in place so that research is conducted to high scientific and ethical standards. It is in response to these goals that this document has been produced. It has been based on the NHS document "Research Governance for Health and Social Care" but has also benefited from input by a variety of groups within the osteopathic profession. The National Council for Osteopathic Research is grateful for the input it has received in creating this document.

The profession is aware that proper research governance is essential to ensure that researchers, research commissioners, funders and participants have confidence in the manner in which research is conducted. The Research Governance Framework reflects this concern and the continuing goodwill of the profession will be needed to ensure that this is implemented successfully. In this way, the profession can demonstrate to the public its commitment to high standards of research practice.

WHAT IS RESEARCH GOVERNANCE?

Clinical governance is the template through which patient care can be improved by demonstrating a commitment to high standards. In a research setting governance can be demonstrated by a commitment to high ethical standards, an appreciation of the need for reflection on good research practice and being able to demonstrate the highest standards of concern for the wellbeing of the research participants. This can be achieved by employing suitable risk assessment and management strategies, and demonstrating a commitment to high standards in developing appropriate research questions, suitable research methodology, data gathering, management and interpretation. A commitment to all of these aspects will foster an environment which safeguards high standards of research practice and will provide a positive working environment in which personal, team and professional development will flourish. The framework is intended not just for research involving patients but also research involving students and other participants. Quality in practice is in concordance with the NHS framework where governance has been a feature since 1998. This relationship is described in Figure 1 below:

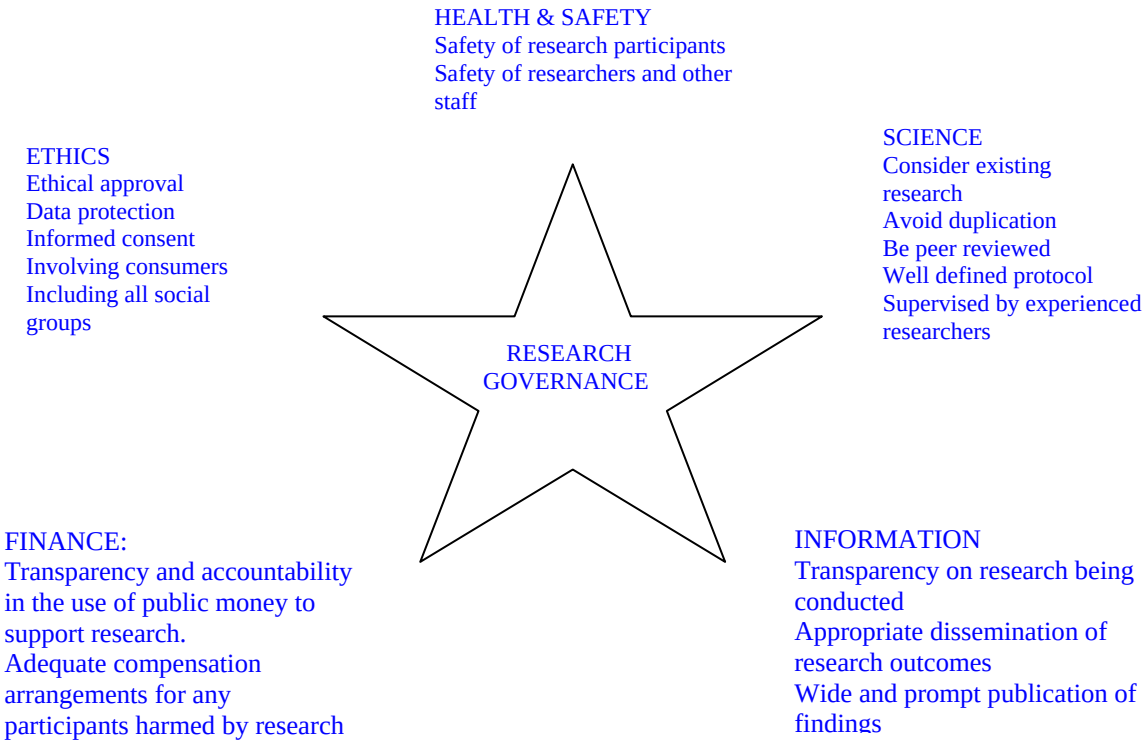


Fig 1. The Areas of Concern within Research Governance

Figure 2. *The Principles of Research Governance for the Osteopathic Community and all Related Staff Engaged in Osteopathic Research.*

The aim of this document is to:

- *Set standards of good practice in osteopathic research*
- *Define and advise on the mechanisms for conducting osteopathic research*
- *Recommend the monitoring and assessment arrangements that are necessary to be implemented in order to deliver high quality research.*

The aim of research governance is to:

- *Improve the quality of research and safeguard both the profession and patients by:*

    - *Increasing ethical and scientific quality*
    - *Promoting standards of good practice*
    - *Reducing adverse events during research and providing researchers with guidance for dealing with such incidents*
    - *Preventing poor research performance and scientific mismanagement.*

- *Research governance has implications for everyone who:*

    - *Participates in research*
    - *Hosts and supervises research in their organisation*
    - *Funds research proposals or monitors those being funded by outside agencies*
    - *Manages and supervises research at all academic levels*
    - *Undertakes research in any environment e.g. academic, private practice*
    - *The NHS has its own document: Research Governance Framework for Health and Social Care created by the Department of Health. Osteopaths working in the NHS should be aware of this document (see www.dh.gov.uk/assetRoot/04/01/47/57/04014757.pdf)*

Adapted from the Department of Health's Research Governance Framework for Health and Social Care, 2nd Edition, 2005 P1

STAKEHOLDERS IN RESEARCH

Recently the Government has shown it is committed to enhancing the contribution of research to healthcare, and to the partnership between services and science. The development of health related research governance has been centred on developments in the NHS. The emphasis on evidence based practice has seen a growth in the demand for evidence. To address this need for research evidence in osteopathy, NCOR has been formed; its stakeholders are shown in Appendix 2.

NCOR is committed to enhancing research among the osteopathic profession. This is reflected in the NCOR mission statements (Appendix 3). Proper research governance is vital for the public to have confidence in, and benefit from, the findings of high quality research in osteopathy. The public has a right to expect rigorous scientific, ethical and financial standards in the pursuit of osteopathic research. The relationship between NCOR and all other research participants can be seen in Figure 3 below.

Who are the Stakeholders in Osteopathic Research?

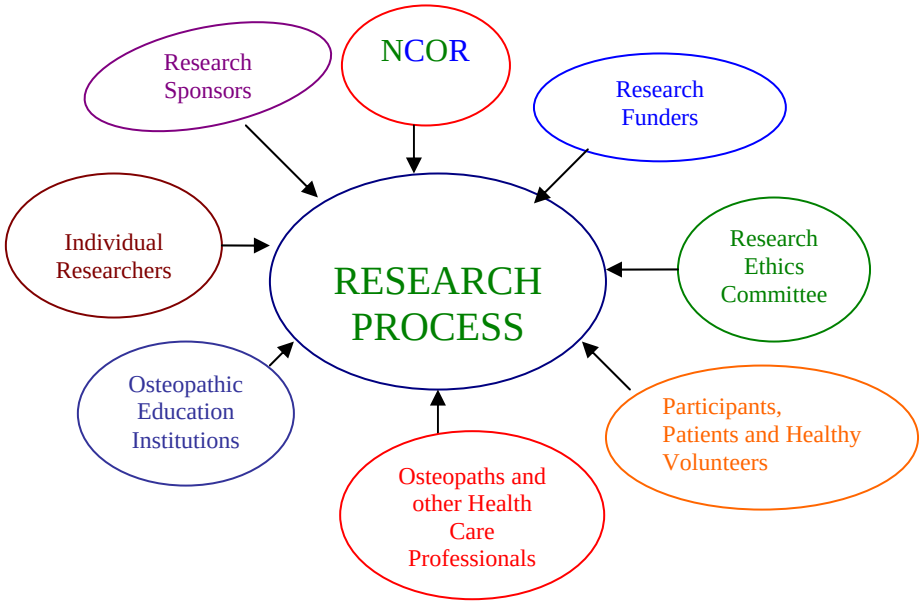


Figure 3. Stakeholders in the Osteopathic Research Process

This document provides a framework for the governance of research in osteopathy based on the Department of Health guidelines issued by the United Kingdom government within their Research Governance Framework for Health and Social Care. The standards in this

framework are concerned with the promotion of osteopathic research while protecting both the public and members of the profession. The standards in this document apply to those who host, conduct, fund, participate in and manage research. It is not restricted to principal investigators, supervisors, managers or to any one professional or academic group. All members of the osteopathic profession, whether in private practice, academic life or in the NHS (no matter how senior or junior) have a role to play in the correct conduct of osteopathic research.

Patients, as research subjects, can also help to ensure that standards are understood and met. The osteopathic profession can, like all other health care professions, learn a great deal from patients about what makes the difference between good and unsatisfactory research. An explanation of further terms can be found in the Glossary of Terms at the back of the document.

PURPOSE AND SCOPE OF THE FRAMEWORK

This Research Governance Framework aims to raise the standards of research in the osteopathic community to the highest possible level. The framework describes the recommended steps to foster accountability within the research environment. Accountability can extend to a number of stakeholders and can be achieved in a variety of ways. The research ethics process fosters accountability to the public at large; peer review of the protocol and dissemination of the final research findings encourages accountability to the wider academic community. This relationship has been summarised in Figure 4 below:

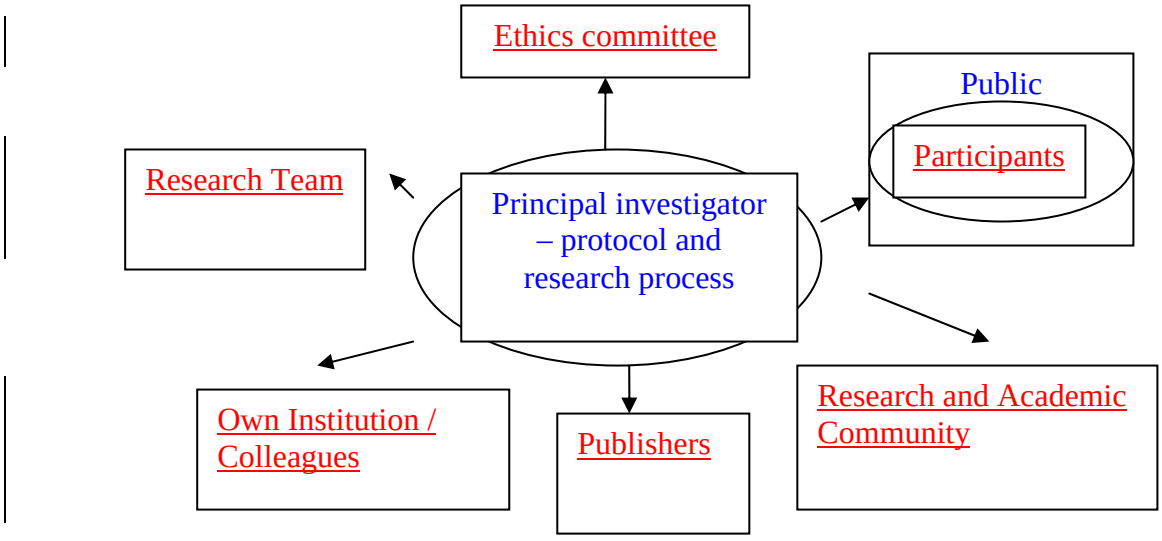


Figure 4. Accountability and Stakeholders in Research

The framework aims to provide a context for the encouragement and facilitation of research that can be both creative and innovative reflecting, amongst other areas, the differing philosophical concepts which exist within the osteopathic profession. The scope of ideas for research studies should be generated, not only from within the osteopathic profession, but also from the needs of the public and other health-related professions and organisations.

Research can be defined as a process to generate new knowledge while critically examining and evaluating existing knowledge and procedures. Innovation in research and its benefits must, however, be scrupulous in attempting to avoid risk and duplication which could alienate the goodwill of patients and research participants.

Research relates to practice in a variety of ways. The manner in which research can contribute to issues of quality improvement, risk assessment, clinical audit and education/training need is summarised in Figure 5 below.

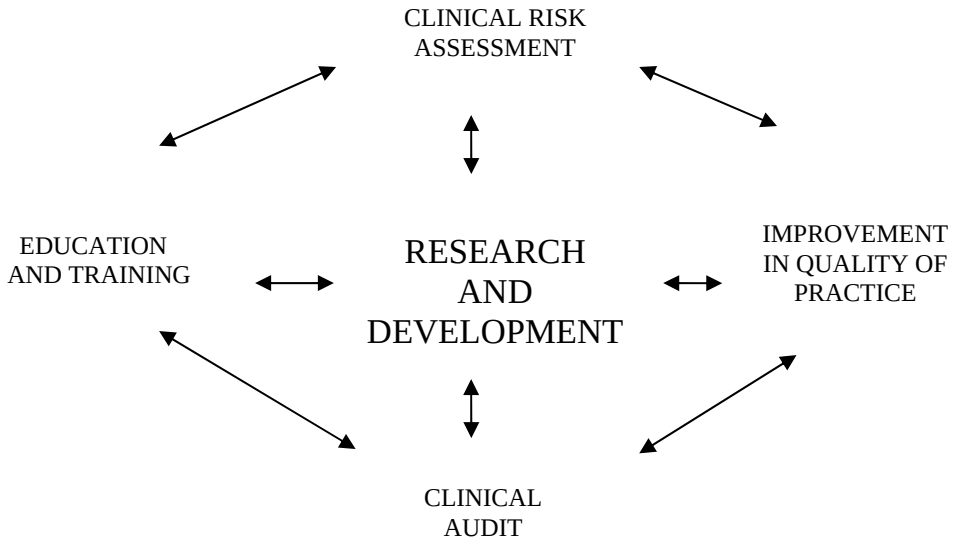


Figure 5.

SCOPE

This framework provides recommendations to prevent poor performance in the conduct of research. These include avoidable adverse events, research misconduct and fraud. The broad topics under which these recommendations fall are:

- Arrangements to clearly define and communicate high quality standards.
- Delivery mechanisms to ensure that these standards are met.
- Arrangements to monitor and assess quality and assess compliance to standards.

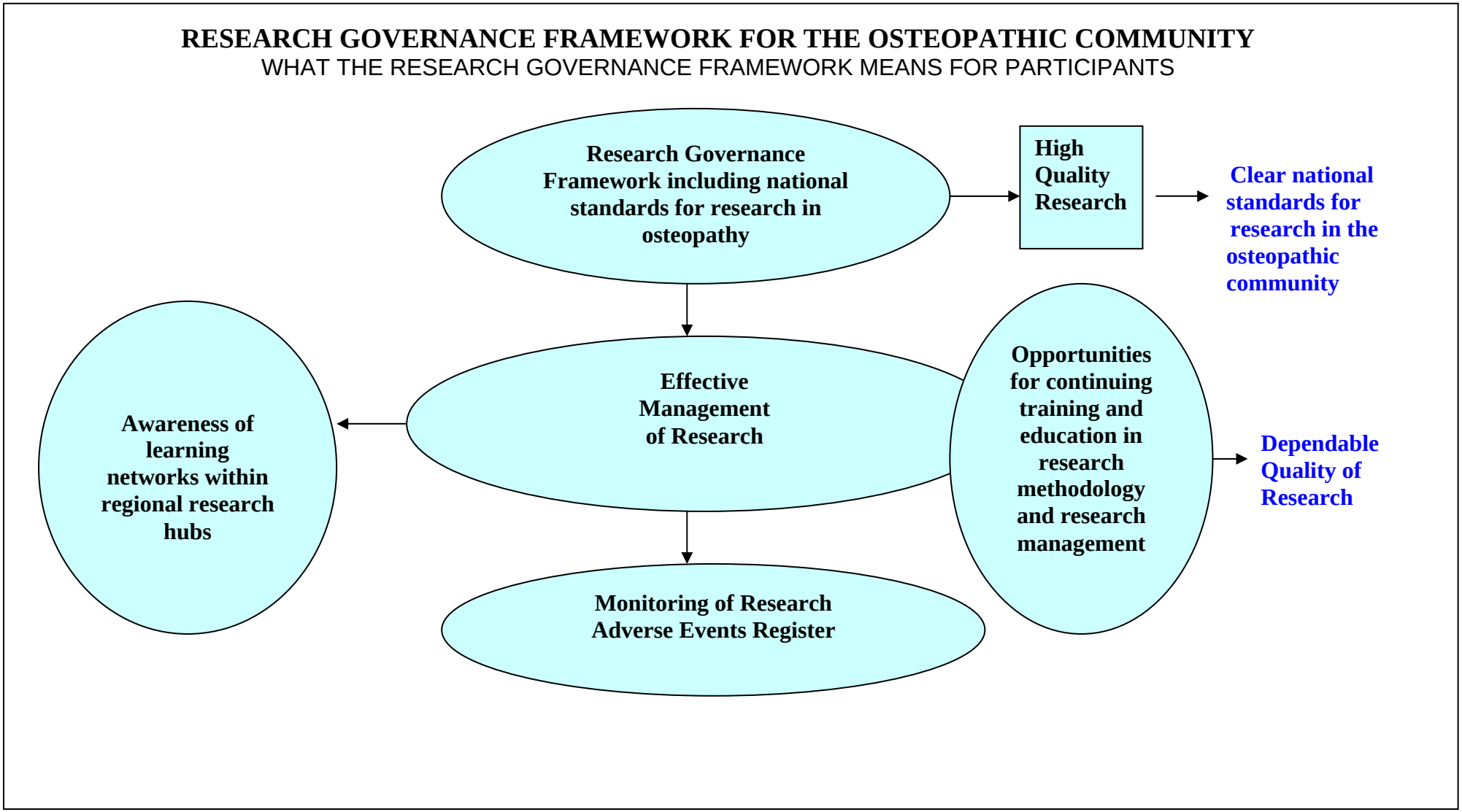
i. Clear guidelines for dealing with the reporting of adverse events are described (see Appendix 4). It is imperative to reassure participants, the public and the profession that such rare events are dealt with clearly, and responsibilities and accountabilities are identified. It is vital that if poor performance is identified lessons are learned from it and shared.

ii. Listed overleaf are some of the individuals involved in osteopathic research. Achieving high quality in research depends on cooperation between all those involved.

- Patients/their relatives, healthy volunteers and/or other carers and organisations representing them
- Members of the public
- Research workers
- Student osteopaths
- Osteopathic Education Institutions (OEI)
- Research councils
- Research charities
- Osteopathic and other health care organisations
- Higher Education Institutions in association with members of the osteopathic profession
- Department of Health
- Health and Social Care Organisations
- Research Ethics Committees

The relationship between all of these groups can be seen in Figure 6 overleaf.

Figure 6. Reference based on "Research Governance Framework for Health and Social Care", Page 5, 2nd Edition, 2005 and adapted for the osteopathic community



GUIDELINES ON STANDARDS FOR RESEARCH GOVERNANCE

Introduction

i. The conduct and delivery of high quality research depends on those responsible being appropriately trained and qualified with the relevant skills and experience to use their profession evaluation judiciously in the delivery of dependable research. The ability to recognise limitations in individual research skills is also important and the need to consult with more experienced peers or supervisors should be considered by researchers. Standards for research governance also include legislative requirements and Department of Health requirements for practitioners working in the NHS. Other helpful guidance produced from a variety of bona fide sources can be found in Appendix 5. Professional judgement is required in the interpretation and application of many aspects of the guidance information.

ii. Health research in the fullest sense of the word is not the province of a single discipline, profession or organisation. Therefore no single document can adequately encompass the full range of legislation, standards and guidelines that need to be applied to the various professional bodies and organisations involved in the wide ranging discipline of research. Six sections are presented here:

- Science.
- Information.
- Health and Safety.
- Finance.
- Delivery Systems in a Quality Research Culture
- Ethics

Appropriate website addresses and references have been included to give advice on current standards and legislation in Appendix 6.

1. Science

Science, in its purest sense, can be described as a method of exploring phenomena by observation and experimentation.

Scientific research utilises these processes to continually evaluate the current state of knowledge in a particular field. Health care services are increasingly drawing on such evaluations to inform the provision of effective and safe treatments for health problems in today's society. Metaphysical ideas about health care cannot be tested by science and are consequently often seen as separate from empirical criticism that is the predominant methodology by which science acts. However, it has also been suggested that a metaphysical idea can inspire the creation of an empirically testable theory[1]. Metaphysical theories can be inspiring, but also arguable and open to criticism [2].

The scientific world has experienced a significant conceptual shift; it is now looking for evidence to discredit a working hypothesis or testable theory rather than just finding evidence to support a working hypothesis. It is important, therefore, to look not only for supporting evidence, but also for evidence that refutes or discredits a theory. Science that looks for evidence of refutation is logically more credible.

However, there is a growing consensus in the scientific world that the study of human beings cannot be completely objective. The context within which human beings find themselves and the influences to which they are exposed e.g. social, political and cultural can be unique to them. This growing awareness is broadening the methodological possibilities within scientific research inevitably resulting in more qualitative and mixed method (qualitative and quantitative) studies being conducted. Osteopathic research is fortunate to have the opportunity to develop at a time when knowledge development is broadening the methodological choices available.

1 *The Logic of Scientific Discovery.* (Translation of *Logic der Forschung).* Hutchinson, London, 1959.
2 *Conjectures and Refutations: The Growth of Scientific Knowledge.* Routledge, London, 1963.

Scientific Considerations for Osteopathic Research:

i. It is essential that existing sources of evidence, especially systematic reviews, are considered carefully prior to undertaking research. Research which duplicates other work unnecessarily or which is not of sufficient quality to contribute something useful to existing knowledge is in itself unethical.

ii. There are a wide variety of considerations when commencing a research study. There are a number of stages in the research process; basic information about this process can be found overleaf, and the place of research methods in the hierarchy of evidence can be found in Appendix 7.

iii. All proposals for osteopathic research must be subjected to review by experts in the relevant fields able to offer independent advice on its quality. Arrangements for peer review must be commensurate with the scale of the research. For many student research projects, the supervisor in the osteopathic educational institution may provide an adequate level of supervision. The process of concurrent ethical review adds to this process.

iv. Data collected in the course of research must comply with the requirements of the Data Protection Act, 1998. Research data must be retained for an appropriate period to allow further analysis by the original or other research teams subject to the consent of the research participants, and to support monitoring of good research practice by regulatory and other authorities. Data must be destroyed at a specified time after data collection has occurred. Further details about the Data Protection Act can be found in Appendix 8.

Steps in the Research Process

The research process can be regarded as a journey in the quest for new knowledge. A number of suitable stages are required in order to produce information that is valuable to a variety of parties and is able to stand up to rigorous scrutiny by the wider scientific community.

The research process is described overleaf in Figure 7

The Research Process

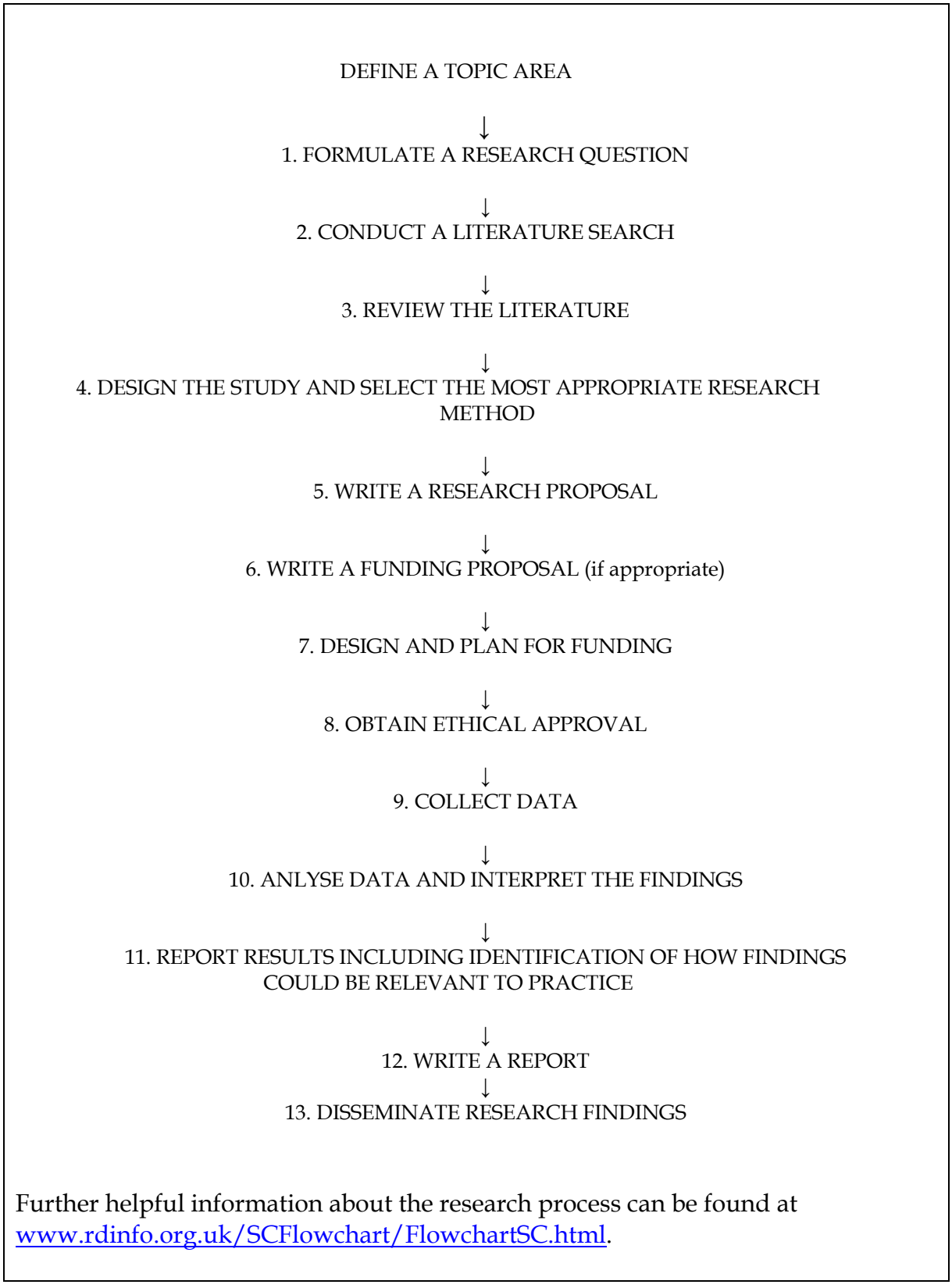


Figure 7. Steps in the Research Process

2. Information

i. Osteopathic and other health care research is conducted for the benefit of patients, users, care professionals and the public in general. There should be free access to information both on the research being conducted and the findings of the research after they have been subjected to appropriate scientific review. The information must also be presented in a format understandable to the public. Reports need to be comprehensible and take language and other needs into account. It can be useful to produce an abstract of the research avoiding jargon and technical language with which patients and the public may be unfamiliar.

ii. Osteopathic research can lead to the development of aids that could be developed commercially. Successful commercial development often depends on the protection of intellectual property (IP) or commercial confidentiality at critical points in the innovation process. The timing of the publication of research findings may need to take this into account. The protocol should contain clear information concerning how issues around IP and copyright will be managed.

iii. All osteopaths pursuing research must be prepared to open their work to critical review through accepted scientific and professional channels. Once established, findings must be made available to research participants and to all those individuals who could benefit from those findings, by means of publication or other appropriate means of dissemination. The intended manner of publication should be made known to research participants before a study begins. The intention to publish negative results should also be explicit.

iv. The requirements of the Data Protection Act 1998 must be followed. If there is any uncertainty, appropriate legal advice must be sought. Where there are ambiguities and differing interpretations of the Act, the actions taken must be those that afford the greatest protection for research subjects.

3. Health and Safety

i. The safety of research subjects must be given priority at all times; health and safety regulations must be strictly observed.

ii. Researchers must be aware of their personal safety when conducting research. If interviews are part of the research process and are to take place outside normal clinic surroundings, adequate chaperoning arrangements should be made.

iii. Advising colleagues of the location of an interview, its starting time and anticipated finishing time is advisable. Researchers should withdraw from any situation in which they feel at risk of abuse or harm.

iv Researchers may also be at risk from less obvious forces during the research process, such as the potential harm from being placed in a compromising situation and from inadvertently causing hurt to others. Researchers are advised to read the Code of Practice for the Safety of Social Researchers (Social Research Association 2002). The need of researchers for psychological support to maintain their wellbeing, beyond the data collection phase of any study, must also be recognised.

iv. It is also important to recognise sensitive cultural situations. For example, in some cultures it is not acceptable for a man to interview an unaccompanied woman. When researchers go into participants' home, social or work environments to collect data, they must respect the privacy, dignity and customs of participants and others in the environment.

v. The nature of risk associated with a research project should be assessed. This will be determined in particular by the level and nature of interaction with human research participants. No standard formula for the evaluation of risk can be recommended. It is important in all instances for an assessment to be made by suitably qualified professionals. The assessment must include the analysis of the aims, methods and the likely impact of the research. A checklist that can assist in this process can be found in Appendix 9.

4. Finance

i. Financial probity and compliance with the law and with the rules laid down by H.M. Treasury for the use of public funds are as important in research as in any other area. This is particularly true if any grants have been awarded to fund research.

ii. Organisations employing researchers, e.g. universities and osteopathic educational institutions must be in a position to compensate anyone harmed as a result of their negligence. Any organisation that stipulates it will offer research compensation on the occurrence of an adverse event must be in a position to do so.

iii. Careful consideration must be given to the appropriate exploitation of intellectual property rights as set out in Appendix 1.

iv. Guidelines for recompense for research participants and/or their carers should also be agreed to cover expenses. Consideration could also be given to whether participants actively involved in the research process should receive payment for their time and expertise to a level consistent with other members of the research team. Tokenism, both in reward/recompense and in consultation, should be avoided. (Consumers in NHS Research). Expenses for research subjects should also be agreed; travel costs and loss of normal earnings must be considered and agreed before involvement in any research commences.

v. The intention to use any inducements for involvement in osteopathic research should be made clear in the initial protocol. The agreement or refusal to allow research based on such rewards should be made explicit by osteopathic educational institutions at this early stage of a research study.

vi. Full economic considerations and costings must be calculated before research begins. It is unacceptable for research to be terminated in the middle of a project due to insufficient funds.

5. Delivery Systems in a Quality Research Culture:

The key elements of a quality research culture can be summarised as:

- Respect for participants' dignity, rights, safety and well-being.
- Valuing diversity in society.
- Personal and scientific integrity.
- Leadership.
- Honesty.
- Accountability.
- Openness.

- Clear support from the organisation(s) supervising or hosting the research or other research bodies e.g. the National Council for Osteopathic Research.

Other appropriate measures include:

i. Independent peer review, appropriate to the scale and complexity of the research proposal, allows any organisation the opportunity to demonstrate that it is satisfied with the scientific and ethical standing of the research, its strategic relevance and value for money.

ii. All accredited colleges of osteopathy and universities must ensure that they are aware of, and have given permission for, all research being conducted in or through their organisation, irrespective of external funding.

iii. Failures of delivery systems (either by intent or oversight), near misses or misconduct should be identified by regular random audit. Such failures can be avoided by implementing clear paper trails for recording the progress of a research study at pre-defined stages. A final report at the end of the study should be prepared at both undergraduate and postgraduate levels.

iv. Dissemination of research findings at all stages of professional training and development is an important aspect of any delivery system.

v. The National Council for Osteopathic Research will promote the development of research hubs to allow good practice in osteopathic research to be demonstrated and for members of the osteopathic profession to learn from one another about this particular area.

vi. The relationship between all aspects contributing to and promoting a quality research culture in the workplace can be seen in Appendix 10.

Monitoring, Inspections and Sanctions

i. Osteopathic educational institutions, universities, the National Council for Osteopathic Research and individual researchers should be able to demonstrate adherence to this framework.

ii. The framework is fundamentally to reassure patients and potential research subjects of their professionalism, quality of

their services and to assure their reputation in high quality research and care.

iii. The framework also attempts to demonstrate the importance of quality assurance mechanisms during the research process. This facet of research is important for other stakeholders in the research process e.g. insurers, academic institutions (who may be acting as collaborators), government bodies (who may be commissioning research), members of other professions and members of the public.

iv. Systems which monitor the quality of clinical work e.g. audit, risk management and staff appraisal can assist in the monitoring of research governance.

v. A coherent and user friendly system is needed to monitor research that falls below acceptable standards. This will enhance public confidence and help to prevent adverse events. Sanctions are needed when and where minimum acceptable standards are not met. Good research practice should be seen as an integral part of the "Fitness Practice Guidelines" as issued by the General Osteopathic Council in May, 2005.

vi. Systems for self-reporting of adverse events, near misses and failure of care during the research process are to be encouraged as an effective learning exercise. This is aimed at preventing recurrences of any such events.

vii. A system for adverse reporting events will be put in place to facilitate this process. This has yet to be formalised.

viii. Organisations sponsoring and hosting research must be aware of the possibility of fraud during the conduct of research. It is advisable for systems to be put in place to detect and investigate possible fraud. Agreed processes should be compiled for action in the event of the discovery of fraud. Information and guidelines concerning scientific misconduct can be found in Appendix 11.

Responsibilities and Accountability

Each of the participants involved in a research project, however peripherally, has a stake in the outcome. Each person has some degree of responsibility for ensuring that the research is carried out in a manner which is scientifically and ethically sound.

The stakeholders in the research include:

- the researcher/principal investigator
- the research participants (patients or other volunteers)
- all the members of the research team
- the research funder(s)
- the employers of the principal researcher (if applicable)
- the research supervisor (or supervisory team)
- the sponsor of the research (university/accredited college/NHS)
- the approving research ethics committee
- responsible personnel in the organisation where the research is being carried out
- the osteopathic profession
- fellow osteopaths and members of other professions with an interest in the research findings
- service providers (e.g. PCTs) with a potential interest in the research findings
- manufacturers with a potential commercial interest in the research findings

Further clarification concerning each of these terms can be found in the Glossary of Terms at the back of this document.

Principal Investigator

The Principal Investigator is the person who is responsible for the research at a designated research site. One Principal Investigator is present at each site.

Responsibilities of the Research Principal Investigator

i. Fundamentally, it is the principal investigator's responsibility to ensure that the dignity, rights, safety and well being of participants is given the highest priority at all times by the research team.

ii. The position of principal investigator would ideally be a senior individual with a suitable track record of research experience. This person will take ultimate responsibility and accountability for the conduct of the research and is answerable to the research sponsor and any care organisation or practice within which the research takes place or through which the research data is accessed.

iii. Principal investigators must have suitable experience and expertise in the choice of appropriate research design and the manner in which the research is conducted. They should be able to either undertake analyses or reporting of the study to the standards set out in this framework, or to be aware of

the need to refer to others who would be delegated the responsibility for those aspects. Others who may take on this responsibility would include supervising academics from other institutions, co-applicant/collaborators and advisory groups with appropriate experience.

1. The principal investigator is responsible for ensuring that:

i. The research is carried out in accordance with this Research Governance Framework. The Principal Investigator is the person responsible for research at a particular site. There is only one Principal Investigator for each research site.

ii. Controlled trials are registered, if appropriate, with the National Council for Osteopathic Research and the National Research Register www.nrr.nhs.uk.

iii. The head of any care organisations involved, the principal of a practice and any other individuals with responsibilities within this framework are informed when the study is planned and that their approval is given before the research commences.

iv. If a study involves patients under the care of a general practitioner or specialist for the condition to which the study relates, those care professionals are informed by the researcher that their patients are being invited to participate in a research study and agree to retain overall responsibility for their care.

v. If a study involves NHS patients or NHS staff, the study should fulfil the Department of Health Research Governance requirements. This will usually involve an application to a local Research and Development Support Unit and fulfilling any requirements for Honorary Contractual arrangements with the NHS. In parallel, the research will be expected to fulfil the requirements of the ethical review process as detailed by the National Research Ethics Service (NRES) (www.nres.npsa.nhs.uk).

vi. When the research involves a carer or child, looked after or receiving services under the auspices of a local authority, the agency director or his/her deputy should be informed about the research and agrees to the person (and/or their carer) being invited to participate, and is fully aware of the arrangements for dealing with any disclosures or relevant information.

vii. Participants' care professionals are given information specifically relevant to their care, which may arise during the research process, unless the participants or relevant Research Ethics Committee, request otherwise.

viii. The study complies with all legal and ethical requirements.

ix. Each member of the research team is experienced and educated in all aspects of the research process to discharge his/her role in the study in a professional manner.
Novice researchers and students must have adequate and easily accessible supervision, support and training.

ix. The research study protocol approved by the relevant ethics committee and the research sponsor must be followed by the researchers without deviations. Any proposed changes, amendments or deviations from the protocol must be submitted for approval to the ethics committee, the research sponsor and to any other appropriate body involved. The principal investigator is responsible for monitoring the progress of a research project.

x. Pre-agreed systems and procedures are in place to ensure accurate and high quality data is collected by the researchers. Arrangements must be in place to protect the integrity and confidentiality of data during the processing, storage and archiving stages of the research process.

xi Transparency on the progress of research outcomes is paramount. Results must be open to critical review through accepted scientific and professional channels on completion of the research. Research findings must be disseminated promptly and appropriate information reported to research participants.

xii. Each researcher involved in a study must be prepared to accept their responsibility to act in an honest manner, thereby aiming to prevent scientific misconduct connected with any aspect of a study e.g. data collection or publication.

xiii. The management of intellectual property, financial resources and any other relevant resources used during the research process must be managed to an agreed standard of integrity.

xiv. All data documentation associated with the study is available for audit at the request of the appropriate auditing authority.

Responsibilities of Research Funders

i. It is the responsibility of organisations that fund and commission research to ensure that the work is an appropriate use of funding resources and represents value for money.

ii. Organisations wishing to fund research, which requires the collaboration of the NHS or social care services in England, must either be willing and able to discharge the responsibilities of research sponsor or collaborate with another organisation which is prepared and able to do so.

iii. Payments of research funding must be made according to pre-agreed contractual arrangements established between the research team and the funder.

Research Sponsor

The sponsor is defined as the agent who ensures all aspects of sponsorship are in place and this is normally the Chief Investigator.

Responsibilities of a Research Sponsor are to ensure

i. The research proposal respects the dignity, rights, safety and well-being of participants and the relationship with care professionals.

ii. The research proposal is worthwhile, of high scientific quality and represents good value for money.

iii. Any research requiring the collaboration of the NHS or social care services in England must have an appointed research sponsor.

iv. The research proposal has been approved by an appropriate research ethics committee.

v. Appropriate arrangements are in place for the registration of clinical trials.

vi. The principal investigator, and other key researchers, have the necessary expertise and experience and have access to the resources needed to conduct the proposed research successfully.

vii. The research sponsor plays a critical role in assuring the quality of the research and the quality of the environment in which the research will be conducted.

viii. Research supervisors have undertaken appropriate induction and training necessary to engage in research supervision.

ix. Sponsors are also responsible for ensuring processes are in place to review significant developments during the research process, especially those which put the safety of individuals at risk, and to approve any necessary modifications to the research design.

x. Students have received appropriate training in the necessary research skills required for successful completion of the project concerned.

xi. The arrangements and resources proposed will allow the collection of high quality, accurate data which is valid and reliable and at an appropriate level in relation to the researcher concerned. The design of the research proposed will be adequate to ensure that the systems and resources being proposed are in place to allow appropriate data analysis and data protection.

xii. Intellectual property rights and their management are appropriately addressed in research contracts or terms of grant awards.

xiii. Arrangements proposed for the work are consistent with the Research Governance Framework of the National Council for Osteopathic Research and Department of Health Research Framework (for osteopaths working in the NHS).

xiv. Organisations and individuals involved in the research all agree the division of responsibilities between them.

xv. There is a clear written agreement identifying the organisation responsible for the ongoing management and monitoring of the study, whether this is the organisation employing the researchers, the sponsor, or another organisation. Sponsors can, however, delegate certain responsibilities for the research design and management of a group to a research team with a proven track record.

xvi. Arrangements are in place for the sponsor and other stakeholder organisations to be alerted if significant developments occur as the study progresses, whether in relation to the safety of individuals or to scientific direction. Appropriate health and safety risk assessments should be carried out.

xvii. An agreement has been reached about the provision of compensation in the event of non-negligent harm and any organisation, including the sponsor itself, offering such compensation has made the necessary financial arrangements.

xviii. Arrangements are proposed for disseminating the findings of the research at a suitable level, in appropriate fora and within a reasonable time frame.

xix. All scientific judgements made by the sponsor in relation to responsibilities set out here are based on independent and expert advice. This includes having in place a rigorous peer review process, supervisory input, ongoing monitoring process regarding research progress and the external examiner system where student research projects are involved.

xx. Steering committees are set up for externally funded projects.

xxi. Assistance is provided to any enquiry, audit or investigation related to the funded work.

xxii. Agreements are in place with respect to authorship of publications and other research output between participants of the research study prior to the research commencing.

xxiii. Arrangements are in place for the safekeeping and storage of the data following the completion of the project in line with the requirements of external organisations, universities or osteopathic educational institutions.

xxiv. Occasionally research will have no external sponsor; in this case a designated care organisation must be willing to act as sponsor for the research. This is sometimes called "own account research."

Responsibilities of Universities, Osteopathic Educational Institutions and other Organisation Employing Researchers

i. Employers of research staff have a responsibility for developing and promoting a quality research culture in their organisation. They must ensure that their staff have the necessary training, career development and support during the research process.

ii. A list of all research undertaken by students as part of their training must be maintained by an academic institution, including identification of the host institution and/or other academic

supervisors. This list could be provided to external organisations at the end of each academic year. This type of list would serve a number of functions including allowing new researchers to see what research has already been completed to allow further development of research or avoid duplication.

iii. Guidelines must also be present and held to account for the professional conduct of research. Clear codes of practice outlining standards of professional conduct, systems for monitoring compliance, dealing with non-compliance, and learning from complaints must all be in place. These responsibilities apply to both private and public sector employers.

iv. Organisations must ensure that principal investigators and researchers they employ fully understand the intricacies of the research process and are competent to discharge their responsibilities commensurate with the research protocol.

v. The extent of the responsibilities for the management and monitoring of research must be agreed between the research sponsor and the employing organisation.

vi. Identification, ownership, protection, exploitation and income that may arise from intellectual property resulting from the research must be clearly agreed between employing organisations and their staff. Systems must be in place to administer this process.

vii. Ensuring arrangements are in place for compensation for research subjects in the event of a claim for negligent harm or non-negligent harm arising from the research study.

viii. Compliance with all current employment and health and safety legislation.

ix. Demonstrating the existence of clear codes of practise in other areas for their staff and to monitor and assess compliance.

x. Ensuring that the principal investigator and/or other research staff are aware of, understand and comply with this framework.

xi. Discharging their agreed role in the management and monitoring of work undertaken by their organisation.

xii. Demonstrating systems for continuous professional development of staff at all levels.

xiii. Having in place systems to detect and address fraud, and other scientific or professional misconduct by their staff.

xiv. Having in place systems to process, address and learn lessons from any complaints brought against their employees.

xv. Permitting and assisting in any investigation arising from complaints received in respect of actions taken by their employees.

Responsibilities of the Academic Supervisor

i. Ensure that the academic institutions are fulfilling their responsibilities as a research sponsor as specified earlier.

ii. Ensure that projects are of scientific quality and clinical relevance through an adequate level of protocol review.

iii. Ensure that the student has adequate academic supervision and support to conduct the study successfully. Evidence for this would be provided in a number of ways for example by the provision of a contract between the supervisor and the student and a record of supervisory meetings. Examples of explicit ethical and proposal review procedures involving the supervisor could also fulfil this criterion.

iv. Ensure that 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 necessary for the completion of the project.

v. Ensure that 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.

vi. Ensure that the project is compliant with all current health and safety legislation, data protection legislation, and other relevant legislation including data storage.

vii. Ensure that if any exploitable intellectual property arising from the research is identified, the NHS consortium, academic organisation and/or other organisations concerned are notified.

viii. Ensure that the project is submitted for ethics approval by the NHS REC system, university, social care organisation system, osteopathic

educational institution's committee or NCOR ethics committee (currently under discussion) system as appropriate.

ix. Ensure that any financial impact on the NHS/osteopathic educational institution or other relevant organisation is agreed and approved by all the parties involved.

x. Ensure that for each project procedures are completed in line with local institutional arrangements. An example would include all sections of the student project agreement pro forma being completed fully and the pro forma being signed by the academic supervisor, clinical/work based supervisor and the student(s). Upon completion of the study the pro forma should be submitted to the nominated university officer. An example of a pro forma for a student project can be found in Appendix 12 and a pro forma for a group project can be found in Appendix 13.

xi. Assist in any investigation arising from any complaint received in respect of actions taken by the student as part of the research activity.

Responsibilities of Practising Osteopaths Engaged in Research.

All practising osteopaths are responsible for the care of their patients when they are participating in research.

Osteopaths must satisfy themselves that the planned research is valid, is likely to be directly or indirectly beneficial to patients' future care, has been the subject of approval by research ethics committees, peer reviewers and any other appropriate scrutinising authorities within their organisation. Once they are satisfied that these criteria have been met, they may then agree to their patients being approached for research purposes.

6. Research Ethics

"The dignity, rights, safety and well being of participants must be the primary consideration in any research study"

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.

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

Research subjects must be treated in a fair and concerned manner.

Conducting Ethical Research:

i. 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:

i. 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. An example of an informed consent form is available in Appendix 14.

ii. Informed consent is normally required in written form, but appropriate alternatives, such as tape recording, can be considered.

iii. Informed consent may be either verbal, signed or written, as long as it is documented. Explicit consent must be sought for the use, in dissemination or teaching, of any photographs, videotapes or audiotapes collected during the research process. Where the

researcher and research participant(s) use different forms of communication e.g. Braille or signing for hearing impairment, specialist advice should be sought.

iv. Similarly if a research participant speaks a language different to the researcher, a qualified interpreter, who is not a family member, should be used.

Children and Other Vulnerable Individuals:

i. In the case of vulnerable individuals such as minors, participants with severe dementia or other disabilities, a legally acceptable representative should be appointed to give consent.

ii. In circumstances where someone has been personally unable to consent to participate in research, but an appointed representative has given assent, the research must not be carried out if the potential participant indicates an unwillingness to participate e.g. by becoming distressed. If circumstances change so that participants become able to give consent, they should be informed of their participation in the research as soon as it becomes possible. Consent should be sought for ongoing participation and/or use of their data. (See Council of Europe Steering Committee on Bioethics 2001, chapterV1, Article21: Research in emergency clinical situations.)

iii. The Royal College of Paediatrics and Child Health (RCPH) provides guidance on procedures researchers must follow to obtain consent. For consent to be freely given, researchers must:

- Offer families no inducements, although expenses should be paid.
- Exert no pressure on families
- Allow families as much time as possible (at least a few days for a major study) to consider whether to take part in the project.
- Encourage families to discuss participation in the project with other family members, primary health professionals or an independent counsellor, for example.
- Explain clearly that it is quite acceptable to refuse to participate or withdraw from the study at any stage, even if they have signed a consent form.
- Explain that no reasons need to be given for their withdrawal from the study.
- Reassure parents that there will be no prejudice to their child's health if they choose to withdraw from the research.
- Encourage parents/guardians to remain with their child during procedures.

- Respond to families' questions, anxiety or distress throughout the study.

For consent to be informed researchers must discuss with families:

- The purpose of the research.
- Whether the child stands to benefit directly from the research, and, if so, in what manner. Clarify the difference between research and treatment.
- The meaning of the relevant research terms and any implications for consent (e.g. placebo, RCT).
- The nature of each procedure, how often and for how long each may occur.
- The potential benefits and harm (both immediate and long term).
- The name of the researcher whom they may contact with enquiries.
- The name of the doctor directly responsible for the child's care.
- How the child can withdraw from the project.

vi. Researchers must be willing to explain and answer questions throughout the project.

vii. It is important to ensure that other staff caring for the child know about the research and can also explain about it if necessary.

viii. Clear written patient information leaflets setting out all relevant information must be given to families to keep. (Further guidance can be found on the NRES website www.nres.npsa.nhs.uk). An example of a patient information sheet can be found in Appendix 15.

ix. It is important to ensure that the results of research should be reported to the families involved wherever possible. (Source: MRC: Medical research involving children). www.mrc.ac.uk.

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.

Patient/Participant Data:

The appropriate use, protection and secure storage of patient data are extremely important. All of those involved in research must be aware of both their legal and ethical duties in relation to patient data. Particular attention must be given to systems for ensuring confidentiality of personal information. Strategies should also be clear to both subject and researcher on the process for dealing with sensitive confidential information arising during the research process if legal concerns arise about information divulged.

Patient/Participant Populations:

Participants or their representatives should be involved where possible in the design, conduct, analysis and reporting of research. Patients are increasingly being encouraged to be involved in research through patient fora, new statutory bodies in each NHS Trust and Primary Care Trust created as part of the Health and Social Care Bill, 2001. If it is not possible to involve patients before and during the research process, it is desirable to consult them for their opinion after they have been involved in research.

Research participants and those conducting research should be aware of and respect the diversity of human culture and conditions in our increasingly multi-cultural society; they must take full account of gender, ethnicity, age, disability and sexual orientation in the design, undertaking and reporting of research. It is particularly important that the body of research evidence available to policy makers reflects the diversity within the population.

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.

Research Involving Animals:

All possible alternatives should be investigated before using animals in research. There are strict controls enforced by the Home Office where animal use is required; the highest standards of animal husbandry, under veterinary supervision, must be maintained at all times. Home Office requirements are listed in Appendix 16.

Sensitive Issues in Research:

i. In the research planning process, the researchers must formulate a policy regarding the action that must be taken in the event of the disclosure of sensitive information which may have potential legal implications.

ii. The research role can create issues of conflict if patients are unwilling to participate in a research study for valid reasons known only to

them. Pressure or coercion should never be brought to bear on any potential research participant. This also underlines the difficulty of conducting research among a researcher's own patients.

iii. Maintaining confidentiality can be difficult, especially in qualitative research where a patient may be clearly identifiable from their data. Identifying participants without compromising their identity must comply with the requirements of the Data Protection Act 1998 (see Appendix 8). Advice should be sought if there is any uncertainty about this matter. This dilemma should be discussed with a potential research participant as part of the information given before consent is sought.

iv. When conducting qualitative research, participants may occasionally be given copies of their data (e.g. interview transcripts) to check for accuracy. This situation should allow the opportunity for the research participant to amend their transcript accordingly, for example include any additional comments or withdraw any information. Certain qualitative research methods also provide participants with summaries of the later stages of data interpretation for verification.

How to Decide if Ethics Approval is Required:

TYPE OF RESEARCH STUDY	PARTICIPANT INFORMED CONSENT NEEDED	APPLICATION TO RESEARCH ETHICS COMMITTEE REQUIRED
Case study/report	Yes	No
Case series	Yes	Yes
Case series	Yes	Yes
Cohort Study	Yes	Yes
Randomised controlled trial	Yes	Yes

Responsibilities Relating to Research Ethics Committees (RECs)

Research should not proceed without prior opinion and approval of a Research Ethics Committee (REC) as described above. Academic or research organisations who have established an appropriate REC.

i. Clearly define their remit and terms of reference that are consistent with the system of ethics committees established through the power of the Secretary of State for Health.

ii. The terms of reference are freely available for inspection by members of the profession, the Department of Health and members of other professions.

iii. Clearly define arrangements for appointing, training, resourcing, supporting and replacing members.

iv. Establish and meet clear performance targets.

v. Act in good faith to provide clear, independent and impartial advice, within the aforementioned remit and terms of reference.

vi. Be aware that their primary responsibility is to protect the dignity, rights, safety and well-being of all research subjects and researchers.

vii. Work diligently and efficiently to prevent undue delay on delivering an opinion on the ethical value of a research proposal.

viii. If a REC is of the opinion that implementation of a research proposal might contravene the law, it should advise both the researcher and the appropriate authority of its concerns. The researcher and the organisation involved will then need to seek legal advice.

ix. The systems for recording operational details of meetings and handling of applications must be clearly demonstrable.

x. RECs must have agreed protocols to identify, record and address any conflicts of interest that could potentially compromise the independence of their advice.

xi. Systems must be in place for all RECs to record not only their decisions but the reasoning behind those decisions.

Further information on RECs can be found at NRES www.nres.npsa.nhs.uk.

Research Ethics Committees are <u>not</u> 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 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 through NRES.

- 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 REC.

- Osteopaths working in private practice should consult their local NHS REC, if they are willing to give an opinion, or the NCOR REC (Yet to be established). Alternatively, osteopaths in private practice can contact their local Osteopathic Educational Institution to see if they are able to offer ethical review.

- The requirements for determining whether a research project is ethical or not can be found in the table in Figure 8 overleaf.

  The steps to be considered for osteopaths in private practice and working in the NHS when seeking ethics approval can be found in Figures 9 and 10 respectively.

Figure 8. SEVEN REQUIREMENTS FOR DETERMINING WHETHER A RESEARCH STUDY IS ETHICAL

REQUIREMENT	EXPLANATION	JUSTIFYING ETHICAL VALUES	EXPERTISE FOR EVALUATION
Social or scientific value.	Evaluation of a treatment, intervention or theory that will improve health and well being or increase knowledge.	Scarce resources and non-exploitation.	Scientific knowledge; citizen's understanding of social priorities.
Scientific/academic validity.	Use of scientific principles and methods, including statistical techniques, to produce reliable and valid data.	Scarce resources and non-exploitation	Scientific and statistical knowledge; knowledge of condition and population to assess feasibility.
Fair subject selection.	Selection of subjects so that stigmatised and vulnerable individuals are not targeted for risky research and the rich and socially powerful not favoured for potentially beneficial research.	Justice	Scientific knowledge; ethical and legal knowledge.
Favourable risk-benefit ratio.	Minimisation of risks; enhancement of potential benefits; risks to the subject are proportionate to the benefits to the subject and society.	Non maleficence, beneficence and non-exploitation.	Scientific knowledge; citizen's understanding of social values.
Independent review.	Review of the design of the research trial, its proposed subject population, and risk-benefit ratio by individuals unaffiliated with the research.	Public accountability; minimizing influence of potential conflicts of interest.	Intellectual, financial and otherwise independent researchers; scientific and ethical knowledge.
Informed consent.	Provision of information to subjects about purpose of the research, its procedures, potential risks, benefits and alternatives so that the individual understands this information and can make a voluntary decision whether to enrol and continue to participate.	Respect for subject autonomy.	Scientific knowledge; ethical and legal knowledge.
Respect for potential and enrolled subjects.	Respect for subjects by 1.Permitting withdrawal from the study; 2. Protecting privacy through confidentiality; 3. Informing subjects of newly discovered risks or benefits; 4. Informing subjects of results of clinical research. 5. Maintaining welfare of subjects.	Respect for subject autonomy and welfare	Scientific knowledge; ethical and legal knowledge; knowledge of particular subject population.

Emanuel EJ, Wendler D, Grady C. *Journal of the American Medical Association*, 2000; 283 (20): 2703.

Figure 9. Ethics Decision Making Tree for Osteopaths in Private Practice.

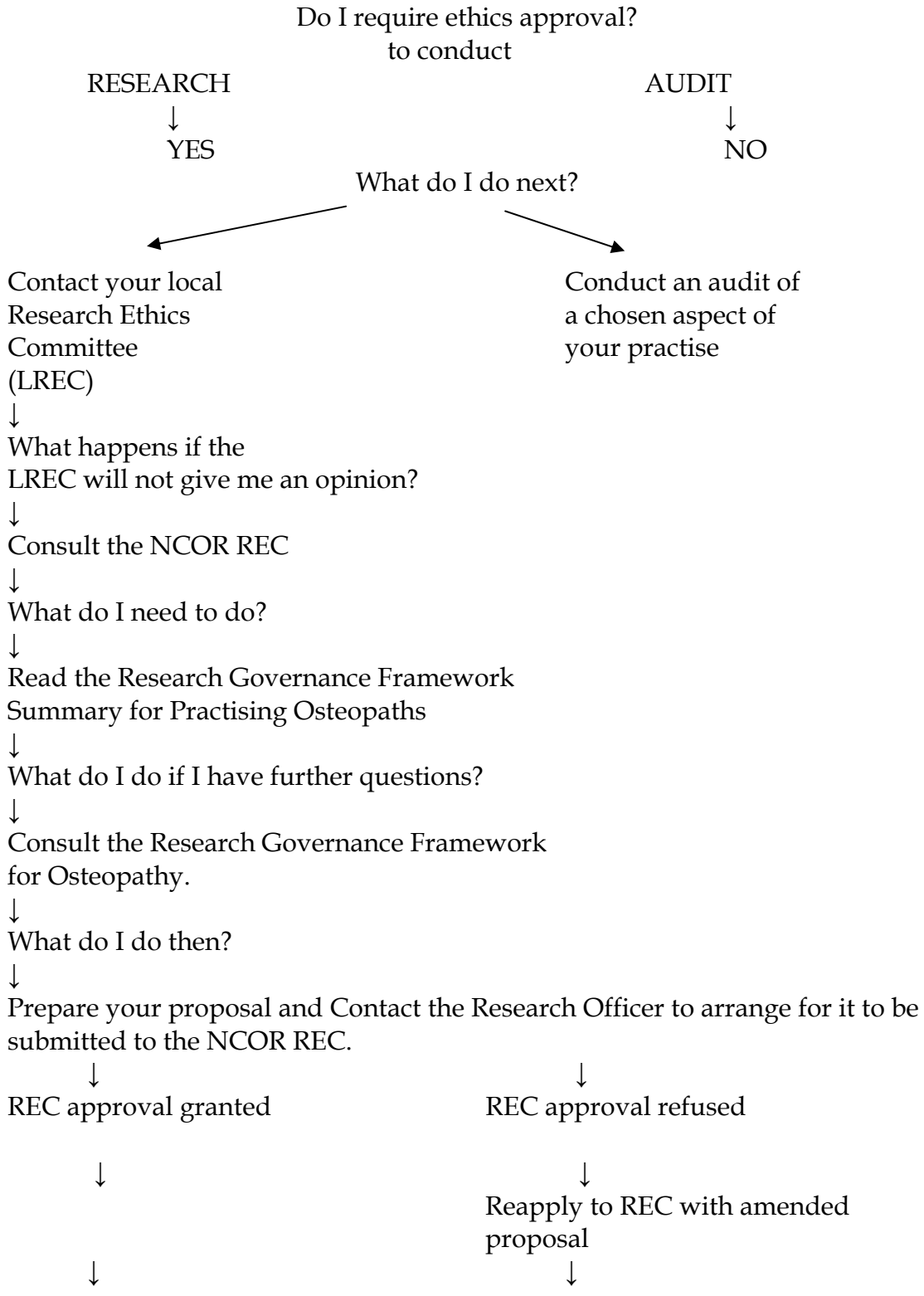
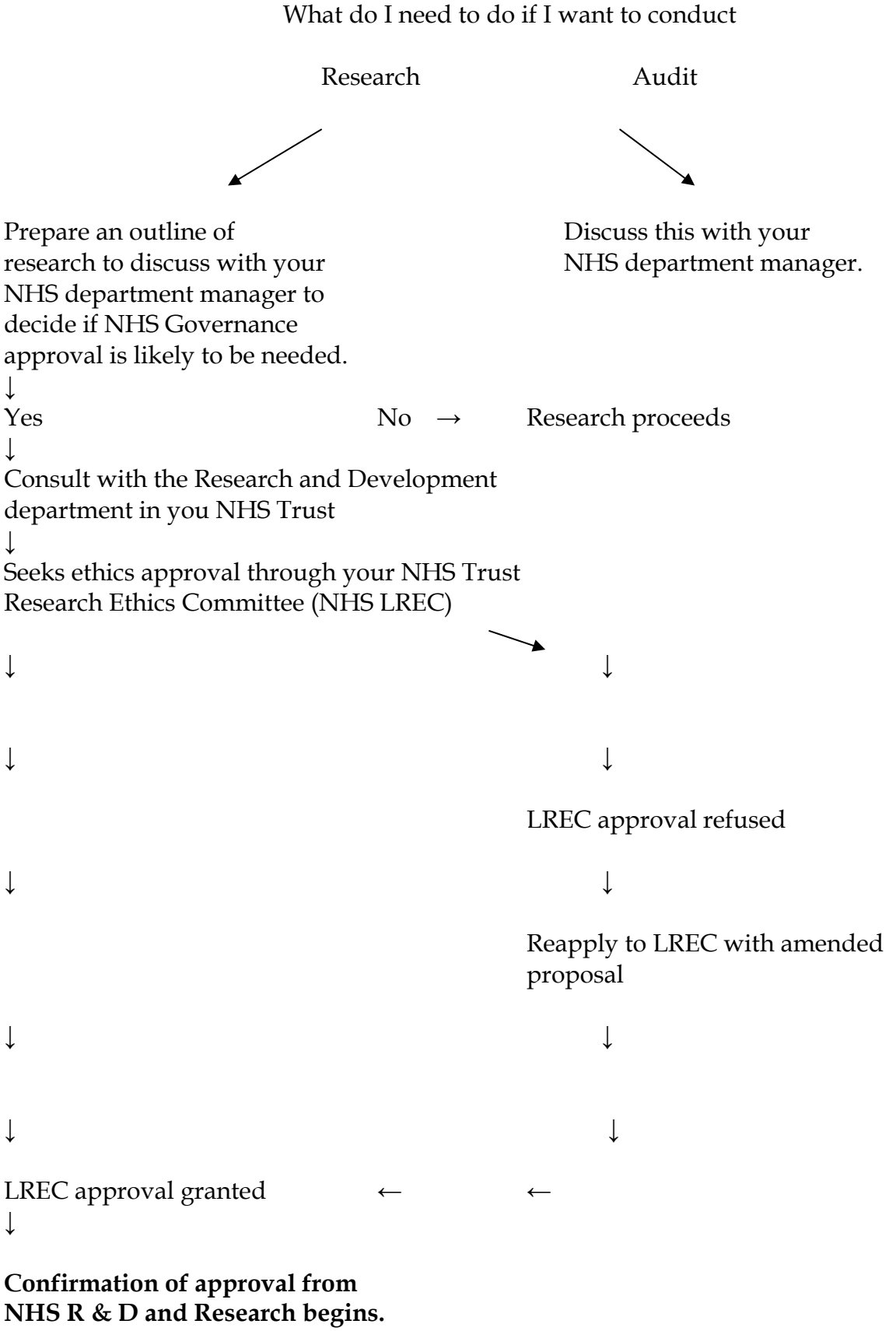


Figure 10. Ethics Decision Making Tree for Osteopaths Working in the NHS.



Defining Research, Audit and Evaluation.

When considering whether ethics approval will be required, it is important to consider whether a study can be described as research, audit or evaluation. The following definitions are intended to describe the difference between the processes.

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 health care 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 in Figure 11 overleaf.

Figure 11. 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.

APPENDIX 1 KEY PRINCIPLES OF RESEARCH

There are numerous principles involved in good quality research. These can be summarised:

Scientific Research must:

- Have suitable arrangements for research to be peer reviewed and aim to achieve high scientific quality.
- Have clearly defined protocols.
- Examine and consider existing sources of evidence so that research is not being duplicated.

Information:

- Research outcomes must be made public, published promptly and to as wide an audience as possible.
- Research presently being conducted must be transparent and in full compliance with due process.
- All research must be open to critical review through appropriate peer review in accordance with Governance requirements.

Health and Safety:

- The safety and wellbeing of all parties involved in research e.g. researchers, research participants and other staff must be a priority at all times

Finance:

- High standards of accountability and transparency must be present at all times especially when using funds from the NHS, charitable organisations or other research funding bodies.
- The exploitation of intellectual property rights must be considered.
- Suitable insurance must be in place to compensate any research participant who has experienced non-negligent harm while involved in the research process.

Delivery Systems in a Quality Research Culture:

- A quality research culture, where excellence is promoted and where there is visible and strong leadership and expert management, is essential if osteopathic researchers are to understand and apply standards correctly. A quality research culture is thus essential for proper governance of osteopathic research.
- Organisations undertaking, sponsoring, funding or hosting research must have appropriate systems in place to ensure that they and their staff understand and follow the standards and good practice set out in this framework.

- Expert independent review is a vital part of the research process. All research sponsors must have systems in place, or have access to such systems, to undergo this process.

Ethical Research must:

- Meet high ethical standards and obtain the approval of osteopathic education institutions, appropriate ethics organisations: the proposed NCOR REC for osteopathic research and NRES (for NHS research).
- Have rigorous arrangements in place for obtaining informed consent in a manner appropriate to selected patient groups and participants.
- Involve consumers, if possible, particularly those involved in support groups e.g. BackCare and with extensive knowledge and experience of their particular disorder e.g. members of the NHS Expert Patient Programme.
- Take account of gender, disability, age, ethnicity, sexual orientation and the Race Relations Act. Resources must be available to accommodate any of the above.
- Aim to contribute new knowledge.

APPENDIX 2 STAKEHOLDERS in NCOR

The British College of Osteopathic Medicine

The British Osteopathic Association

The British School of Osteopathy

The College of Osteopaths Educational Trust

The European School of Osteopathy

The General Osteopathic Council

The London College of Osteopathic Medicine

The London School of Osteopathy

Oxford Brookes University

The Surrey Institute of Osteopathic Medicine

APPENDIX 3 NCOR MISSION STATEMENTS

1. To establish and develop a comprehensive information resource for osteopathic research in order to promote a mutual research dialogue within the osteopathic profession and with other related professions.

2. To create a forum that will develop and nurture a pan-professional osteopathic research culture. facilitate linkage of research to practice and identify national research priorities.

3. To develop a Research Governance Framework and Code of Good Practice in research for osteopathy which links with frameworks already developed by the National Health Service and the Research funding councils.

4. To increase and improve the profile of osteopathic research at national and international levels with policy makers, HEIs, the NHS and fund-holders.

5. To increase collaboration in research amongst osteopathic providers and HEIs nationally and with like minded researchers internationally to improve the teaching, learning and research nexus and the quality of osteopathic research generally.

6. To improve the quality and quantity of research output.

7. To develop appropriate channels for research dissemination e.g. websites, journals etc.

8. To identify and nurture sources of funding for research activities.

APPENDIX 4 GUIDELINES FOR REPORTING ADVERSE EVENTS

An adverse event or serious adverse event can be described as an occurrence with an unexpected outcome.

- Single case reports of serious adverse events (SAE) to a treatment intervention with an unexpected outcome (e.g. death).
- An increase in the rate of occurrence of an expected adverse event, which is judged to be clinically important.
- Post study sudden unexpected serious adverse reactions (SUSARS).
- A new event related to the conduct of the trial that is likely to affect the safety of subjects. This could be associated with the trial procedures and which could modify the conduct of the trial.

Definition of Serious Adverse Event (SAE):
An adverse reaction can be described as serious if it:

- results in death
- is life threatening
- requires hospitalisation
- results in persistent or significant disability or incapacity

The National Research Ethics Service (NRES) advises that for all studies involving a serious adverse event (SAE). " The Chief Investigator (CI) should report any SAE that is both related to the research procedures and is unexpected. Send the report to the Research Ethics Committee that gave a favourable opinion of the research within 15 days of the CI becoming aware of the event." Further guidance can be found at www.nres.npsa.nhs.uk/applicants/review/after/safety.htm#other.

An example of a form for reporting a serious adverse event can be found at www.nres.npsa.nhs.uk/docs/forms/Safety_Report_Form_(non-CTIMPs).doc.

APPENDIX 5 REFERENCES FOR FURTHER SOURCES OF INFORMATION

An Organisation with a Memory – Report of an Expert group on learning from adverse events in the NHS 2000
www.dh.gov.uk

College of Occupational Therapists Research Ethics Guidelines 2003

Department of Health, 2001. "Seeking Consent: Working with Children."

General Medical Council "Good Medical Practice" 2001
www.gmc-uk.org

General Osteopathic Council "Pursuing Excellence" 2002

GOsC "Standard 2000 – Standard and Proficiency" 2001
www.osteopathy.org.uk/about_gosc/standard_2000.pdf

ICH GCP Guidelines 1999

Medical Research Council Ethics Series: MRC Policy and Procedure for Inquiring into Allegations of Scientific Misconduct." MRC, 1997.

MRC Ethics Guide: Medical Research Involving Children. MRC, 2004.

MRC Guidelines for Good Clinical Practice in Clinical Trials 1998
www.mrc.ac.uk

Oxford Brookes University Research Ethics
www.brookes.ac.uk/research/ethics/ethicshome.html

QAA Code of Practice for the assurance of academic quality and standards in higher education. 2001
http://www.qaa.ac.uk/academicinfrastructure/codeOfPractice/default.asp

Research and Development for a First Class Service- R & D Funding and the New NHS 2000

Research and Development Forum documents
www.rdforum.nhs.uk.

Royal College of Paediatrics and Child Health: Ethics Advisory Committee. "Guidelines for the ethical conduct of medical research involving children."
Reprinted from *Archives of Disease in Childhood* 82 (2): 177-182. 2002

The Chartered Society of Physiotherapists:

Research and Ethics Committees
www.csp.org.uk

University of Brighton Documents 2005
www.brighton.ac.uk

APPENDIX 6 A TO Z OF Websites

A

Association of Medical Research Charities
http://www.amrc.org.uk/aboutus/publicationsandarticles.html
American Statistical Association
http://www.amstat.org

B

Biotechnology and Biological Sciences Research Council
http://www.bbsrc.ac.uk
British College of Osteopathic Medicine
http://www.bcom.ac.uk
British Osteopathic Association
http://www.osteopathy.org
British Psychological Society
http://www.bps.org.uk/index.cfm
British School of Osteopathy
http://www.bso.ac.uk

C

Central Office for Research Ethics Committees (COREC) refer to NRES
Centre for Reviews and Dissemination
http://www.york.ac.uk/inst/crd/ehcb.htm
Chartered Society of Physiotherapists
http://www.csp.org.uk
Clinical Trials
http://212.219.75.225
Clinical Trials in US
http://clinicaltrials.gov
Cochrane Collaboration
http://www.cochrane.org
College of Osteopaths Educational Trust
http://www.collegeofosteopaths.ac.uk
Commission for Racial Equality
http://www.cre.gov.uk
Committee on Standards in Public Life
http://www.public-standards.gov.uk
Consort Statement
http://consort-statement.org/
Consumers of Ethics in Research (CERES)
http://www.ceres.org.uk
Current Controlled Trials
http://www.controlled-trials.com

D

Data Archive
http://www.data-archive.ac.uk

Department of Health
http://www.dh.gov.uk
Department for Business, Enterprise and Regulatory Reform
http://www.dti.gov.uk/index.html

E
Economic and Social Research Council
http://www.esrc.ac.uk
European School of Osteopathy
http://www.eso.ac.uk

F
Food and Drugs Administration U.S.
http://www.fda.gov

G
General Osteopathic Council
http://www.osteopathy.org.uk
General Medical Council
http://www.gmc-uk.org

H
Higher Education and Research Opportunities
http://www.hero.ac.uk

I
Institute of Health Care Management
http://www.ihm.org.uk/

L
London College of Osteopathic Medicine
www.lcom.org.uk
London School of Osteopathy
http://www.lso.ac.uk

K
Kings Fund
http://www.kingsfund.org.uk/

M
Medical Research Council
http://www.mrc.ac.uk

N

National Council for Osteopathic Research
http://www.ncor.org.uk
National Electronic Library for Health
http://www.library.nhs.uk/Default.aspx
National Electronic Library for Complementary and Alternative Medicine
http://www.library.nhs.uk/cam
National Institute for Health and Clinical Excellence
http://www.nice.org.uk
Nuffield Foundation
http://www.nuffield.org.uk

O
Official UK Statistics
http://www.statistics.gov.uk

Q
Quality Assurance Agency for Higher Education
http://www.qaa.ac.uk

R
Royal College of Nursing
http://www.rcn.org.uk
Royal College of Pathologists
http://www.rcpath.org
Royal College of Paediatrics and Child Health
http://www.rcpch.ac.uk
Royal Statistical Society
http://www.rss.org.uk

S
Social Research Association
http://www.the-sra.org.uk
Surrey Institute of Osteopathic Medicine (SIOM)
http://www.nescot.ac.uk

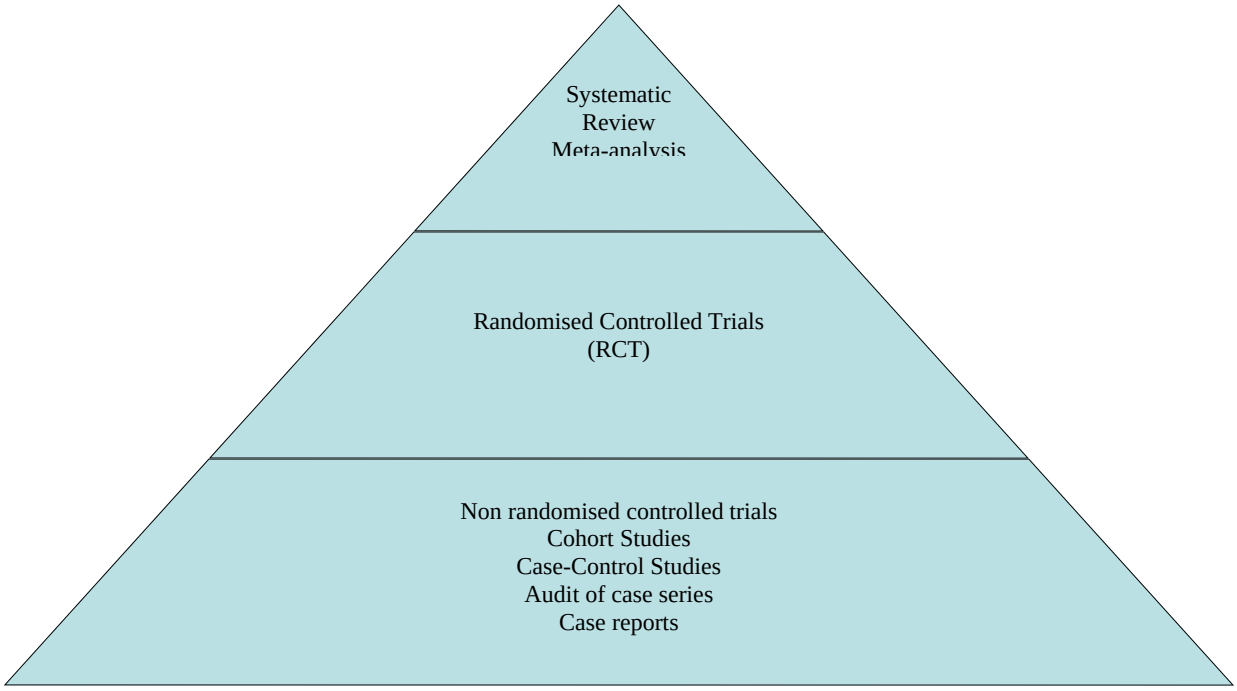
U
Universities UK
http://www.universitiesuk.ac.uk/links
University of Brighton
http://www.brighton.ac.uk.

W
World Health Organisation
http://who.int/tdr/publications/publications/pdf/ethics.pdf
World Medical Association

http://www.wma.net
World Osteopathic Health Organisation
http://www.woho.org

APPENDIX 7 A HIERARCHY OF EVIDENCE

Ia: evidence from systematic review and meta-analysis of randomised controlled trials.
Ib: evidence from at least one randomised controlled trial.
IIa: evidence from at least one controlled study without randomisation.
IIb: evidence from at least one other type of quasi-experimental study.
III: evidence from non-experimental descriptive studies, such as comparative studies, correlation studies and case control studies.
IV: evidence from expert committee reports or opinions and/or clinical experience of expected authorities.



Diagrammatic representation of a hierarchy of evidence.

APPENDIX 8 DATA PROTECTION ACT, 1998.

This aims to protect the confidentiality of personal data stored on living individuals. Personal data encompasses any data that can relate to a living individual who can be identified from that data. This includes all formats i.e. electronic, paper, film, tape, text, still and moving image. Sensitive personal data has a very specific meaning in terms of the Act: racial or ethnic origin; religious beliefs or beliefs of a similar nature; trade union membership; physical or mental health or condition; sexual life; commission of any offence; any proceedings for any offence committed or alleged, the disposal of such proceeding or the sentence of any court in such proceedings. There is a legal duty to abide by the Act. There are eight principles of good practice in the Data Protection Act (DPA) each of which will be considered in turn.

Principle 1

Personal data shall be processed fairly and lawfully, and, shall not proceed at all unless at least one of the following applies:

- The data subject has given consent **OR**
- It is necessary:
    - For the performance of a contract with the data subject.
    - To protect the vital interests of the data subject.
    - To carry out public functions.

Principle 2

Personal data shall be obtained for one or more specified and lawful purposes:

- Only collect the data necessary for your research.
- Ensure research participants understand why you are collecting this information and what you are using it for.
- Be open and honest about exactly what you are using data for.

Principle 3

Personal data shall be adequate, relevant and not excessive in relation to the purpose for which they are processed.

- Only collect and retain essential personal information.
- Anonymise or code data wherever possible.
- Anonymous data – personal data that has been coded by others outside the research team.
- Coded data – Identity is disguised by a code but a decoding sheet is available.

Principles 4 & 5

Personal data shall be kept accurate and where necessary, kept up to date.

- Up to date details at appropriate times.

Personal data shall not be kept longer than necessary for that purpose.

- Only retain personal information as long as necessary, destroy if not needed.

Principle 6

Personal data shall be processed in accordance with the rights of the data subjects under this Act.

- Subject has a right of access to their personal data.
- Prevent processing likely to cause damage/distress.
- To take action for compensation if individual suffers damage or distress.
- To take action to rectify, block, erase or destroy inaccurate data.

Principle 7

Appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to personal data.

- Organisations should have measures in place to protect personal data. Keep data safe and process securely.
- Measures such as password protected computer. Do not save data on lap-tops. Security of data keys and floppy disks, backing up data, archiving.

Principle 8

Personal data shall not be transferred to a country outside the European Economic Area (EEA), unless that country ensures an adequate level of protection for the rights, freedom of data subjects in relation to the processing of personal data.

- Explicit written consent for this is essential.
- All data sent outside the EU must be coded.

There are also seven rights under the Data Protection Act

1. The right to subject access. This allows people to find out what information is held about them on computer and within some manual records.

2. The right to prevent processing. Anyone can ask a data controller not to process information relating to him or her that causes substantial unwarranted damage or distress to them or anyone else.

3. The right to prevent processing for direct marketing. Anyone can ask a data controller not to process information relating to him or her for direct marketing purposes.

4. Rights in relation to automated decision-taking. Individuals have a right to object to decisions made only by automatic means e.g. there is no human involvement.

5. The right to compensation. An individual can claim compensation from a data controller for damage and distress caused by any breach of the act. Compensation for distress alone can only be claimed in limited circumstances.

6. The right to rectification, blocking, erasure and destruction. Individuals can apply to the court to order a data controller to rectify, block or destroy personal details if they are inaccurate or contain expressions of opinion based on inaccurate information.

7. The right to ask the Commissioner to assess whether the Act has been contravened. If someone believes their personal information has not been processed in accordance with the DPA, they can ask the Commissioner to make an assessment. If the Act is found to have been breached and the matter cannot be settled informally, then an enforcement notice may be served on the data controller in question.

Further information on the Data Protection Act can be found at the Information Commissioner's website www.informationcommissioner.gov.uk

APPENDIX 9 RISK ASSESSMENT CHECKLIST

As part of the research project, will the researcher, patient or other human participant be subject to:

1. invasive procedures? □

2. physical or manual handling? □

3. the administering of substances internally? □

Is the research likely to result in:

4. physical damage or harm? □

5. slip or trip accidents? □

6. exposure to hazardous or toxic materials, such as radioactive materials? □

7. psychological distress due to questioning about, for example, beliefs, painful reflections or traumas, illness or sexual behaviour? □

8. pressure or stress being placed on frail or vulnerable individuals, for example, those with mental health problems ? □

Sufficient safeguards and monitoring procedures must be put in place in relation to any such anticipated risks, and a written record kept.

Assessed by:

Signature 1 .....

Job title .....

Signature 2 .....

Job title .....

APPENDIX 10 STANDARDS IN A QUALITY ORGANISATION UNDERTAKING RESEARCH

SCIENCE

There is a commitment to the principle and practice of independent peer review, with scrutiny of the suitability of protocols and research teams for all work in the organisation.

There is close collaboration with partner organisations in higher education and care to ensure quality and relevance of joint work and avoidance of unnecessary duplication of functions.

The organisation plays its role in developing research capacity with appropriate training and updating.

Systems are in place to monitor compliance with standards and to investigate complaints and deal with irregular or inappropriate behaviour in the conduct of research.

The organisation assesses its research outputs and their impact and value for money.

QUALITY RESEARCH CULTURE

The organisation supports and promotes high quality research as part of a service culture receptive to the implementation of best practice in the delivery of osteopathic care. There is strong leadership of research and a clear strategy linking research to professional priorities and needs, clinical governance and the delivery of best value to patients. The organisation's research strategy values diversity in its patients or users and its staff and promotes their active participation in the development, undertaking and use of research.

ETHICS

All research which involves patients, users or osteopaths or their tissues or data is referred to independent ethical review to safeguard the dignity, rights, safety and well-being of the participants.

Osteopathic research is pursued with the active involvement of service users and carers, including, where appropriate, those from hard to reach groups such as the homeless.

If animals' use is unavoidable the highest standards of animal husbandry are maintained under veterinary supervision.

FINANCE

The organisation is aware of the activity involved in supporting research and of what it costs. Research expenditure is planned and accounted for.

The organisation demonstrates financial probity and compliance with the law and rules laid down by HM Treasury. It complies with all audit required by external funders or sponsors and has systems in place to deter, detect and deal with fraud.

When research findings have commercial potential the organisation takes action to protect and exploit them, in collaboration with its research partners and – when appropriate – commercial organisations.

INFORMATION

Information is available on all research being undertaken in the organisation. This is held on a database, which contains details of funding, intellectual property rights, recruitment, research outputs and impact.

The organisation ensures that the patients, users and osteopaths have easy access to information on research. Special arrangements are made to ensure access to information for those not literate in English or who may need information in different formats because of a disability e.g. Braille.

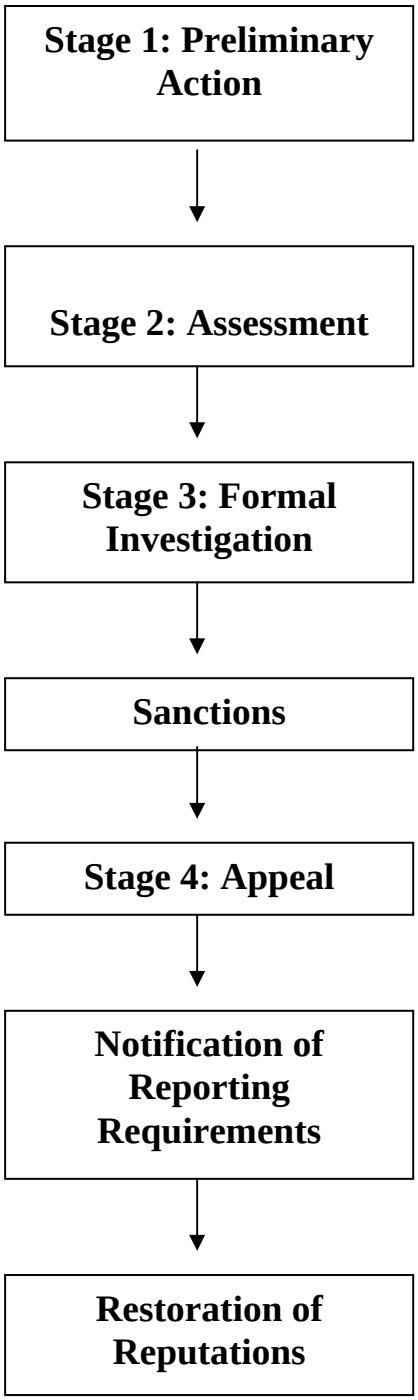
Those agreeing to be involved in research are informed of the findings at the end of the study.

An information service provides access from a single point to all up-to-date regulatory and advisory documentation pertaining to research governance, together with procedural guidance e.g. for applications to research ethics committees. There is a research dissemination strategy which addresses different media and writing styles for different audiences.

APPENDIX 11 SCIENTIFIC MISCONDUCT

Allegations of scientific misconduct are, thankfully, rare but their satisfactory resolution is necessary as a responsibility to patients, members of the scientific community, research funding bodies and Parliament.

The Medical Research Council recommends procedures that reflect the need for expert knowledge in the resolution of these issues. Their policy is designed to apply to all employees, students, visiting researchers and research fellows working in the same environment when the misconduct is alleged to have taken place. The MRC recommends the following stages:



Stage 1: Preliminary Action

i. Determine that the allegation falls within the definition of scientific misconduct. This should be determined by the research director/supervisor.
ii. Decide if an assessment of the allegation is warranted.
iii. Inform the individual against whom the allegation has been made to allow them to respond.
iv. If the response is unsatisfactory, refer the matter for independent assessment.
v. If an assessment is judged to be warranted, arrangements for **immediate** sequestration of all research data (including records held on computer discs etc) must be made.
vi. If an assessment is judged to be unwarranted, the justification for this should be recorded; the individual against whom the complaint is made should be informed of this decision.

Stage 2: Assessment

i. The assessment is designed to determine whether there is *prima facie* evidence of scientific misconduct.
ii. The director/supervisor will inform the person against whom the allegation is made (the respondent) in writing. The complainant will also be reminded of their obligation to cooperate with the assessment.
iii. An assessment committee will be appointed including two individuals who have no conflict(s) of interest and appropriate expertise for the case.
iv. The respondent will be informed of the committee membership by the director/supervisor.
v. The respondent can submit a written objection to any of the committee members.
vi. The challenged person can be replaced by the director/supervisor.
vii. Alternatively, the respondent's objection can be overruled; the reasons for this should be recorded and retained as part of the assessment record.
viii. The assessment should limit its scope to evaluation of the facts to determine whether there is sufficient evidence to warrant an investigation.
ix. The committee will normally interview the respondent, key witnesses and examine all relevant research materials.
x. The assessment committee will complete the assessment and submit its report in writing within 60 days.
xi. The report should record what evidence was reviewed, summarise relevant interviews and conclude, from the assessment, whether an investigation is warranted.

xii. A copy of the report will be given to the respondent; their comments must be submitted to the director/supervisor within 20 days of receipt of the report. This will be attached as an addendum to the assessment record.
xiii. The director/supervisor will decide whether to conduct an investigation, drop the matter or pursue an alternative course of action after examining the report and the respondent's comments.
xiv. The complainant and the respondent will be informed in writing of the decision.

Stage 3: Formal Investigation

i. The formal investigation is conducted to determine whether scientific misconduct has been committed, by whom and the seriousness of the conduct.
ii. If an investigation is to be conducted, the director/supervisor will write to both the complainant and respondent and also remind them of their obligation to co-operate.
iii. The director/supervisor will define the subject matter for investigation in a written charge to the investigation committee amend will attach a copy of the assessment report.
iv. Following notification, the director/supervisor will appoint an investigation committee of at least three persons, some of whom may have been members of the assessment committee. Once again, members of this committee should have no conflicts of interest and have sufficient expertise for the investigation concerned. A Chair will be appointed.
v. The respondent will be informed of the committee membership and have the opportunity to submit a written objection concerning any members to the director/supervisor.
vi. The director/supervisor may replace the member, subject of the objection, with another suitable candidate.
vii. Alternatively, the director/supervisor may choose to over-rule the respondent's objection and must record this as part of the report.

- Once the investigation committee has been appointed, the process will usually begin within 30 days of the completion of the assessment.
- The investigation will normally include examination of all documentation e.g.
- research proposals
- publications
- correspondence
- memoranda
- details of telephone calls
- The respondent and complainant will be interviewed.
- Other individuals involved with the research process and likely to have key information will also be interviewed.

- Verbatim records of these interviews will be included as part of the investigation.
- An investigation will normally be completed within 90 days of it commencing. The clock will start from the appointment of the instigation committee.
- The 90 day period will include:
    - conducting the investigation,
    - statement of the findings,
    - making the report available for comment by the respondent and submission of the report to the director/supervisor.
- The report must state
    - how the investigation was conducted
    - how and from whom relevant information was obtained
    - statement of the findings
    - explanation concerning the basis of the findings
    - an accurate agreed summary of the views of any individual(s) alleged to have engaged in misconduct
    - full verbatim reports of the interviews
- A copy of the report and evidence considered will be given to the respondents. They will have the opportunity to comment on the report.
- Comments must be received by the director/supervisor within 20 days of receipt of the report; they will be attached as an addendum.
- A meeting can be arranged, at the respondent's request, with the director/supervisor, one member of then investigation committee and the respondent's representative.
- This meeting can allow the respondent the opportunity to challenge claims that are felt to be unsubstantiated. A record of the meeting will be kept for the report.
- A final decision on the allegation will be provided by the Director/supervisor to the respondent within 10 days and will outline any measures that will be taken.

Sanctions

- If allegations of alleged misconduct are found to be substantiated by the director/supervisor, appropriate sanctions will be determined and applied.
  These could include any of the following:
    - removal from the research study
    - final written warning
    - special monitoring of future work
    - removal of eligibility for pay progression for one year
    - withdrawal of funding for the study
    - down-banding of appointment
    - referral to the GOsC Practice and Ethics Committee

- Where a director/supervisor can recommend termination of employment if the nature of the scientific misconduct is deemed to be so serious that lesser sanctions are insufficient.

Appeal

- An appeal board can respond to an application from the respondent if he/she feels that the decisions and/or sanctions are inappropriate.
- The complainant cannot appeal against the decision and/or sanctions.
- An appeal board can be convened consisting of two or more persons.
- The respondent will be notified of the proposed composition of the appeal board.
- The appeal process will normally commence within 20 days of receipt of an appeal by a respondent.
- The appeal will normally include:
    - examination of all documentation called into question by the respondent
    - oral evidence by the respondent
    - Any additional relevant supplementary material supplied by the respondent
- An appeal should normally be completed within 90 calendar days from when it commenced
- The appeal report must state:
    - how the appeal was conducted
    - describe how and from whom further relevant information was obtained
    - state the findings
    - explain the basis for the findings

- A final decision will be made which shall be final.

Notification and Reporting Requirements

- **Where there has been no appeal**
- When a final decision has been made, once the investigation has been completed, the respondent will be informed by the director/supervisor within 20 working days.
- A decision will be made whether to inform journal editors, professional associations, research collaborators or other concerned parties about the final decision of the case.
- Any relevant funding bodies will need to be notified of the final decision.

Where an appeal has been heard
- Action will be recommended

APPENDIX 12 TEMPLATE FOR CONFIRMATION OF STUDENT PROJECT

This form should be type written.

1. The Applicant
Surname: **Forename(s):**

2. Project Title:

3. Start date for project:

4. Mode of Study:

5. Synopsis of Project: (No more than 300 words)

Signature of student: _____

Signature of 1st Supervisor _____

Signature of 2nd supervisor (if applicable) _____

This form should be signed by two members of staff in the relevant research area.
A signed copy of this document should be kept as part of the supervisory records.

APPENDIX 13 TEMPLATE FOR CONFIRMATION OF GROUP PROJECTS

This form should be typed

1. The Applicants
Surname: **Forename(s):**

2. Project Title:

3. Start date for Project:

4. Mode of Study:

5. Synopsis of Project: (no more than 300 words)

Signature of students: _____

Signature of 1st Supervisor _____

Signature of 2nd Supervisor _____
(if applicable).

APPENDIX 14 SPECIMEN INFORMED CONSENT FORM

(Form to be produced on headed paper)

Centre Number: :
Study Number:
Patient Identification Number for this trial:

CONSENT FORM

Title of Project:

Name of Researcher(s): **Please initial the box**

1. I confirm that I have read and understand the information sheet dated ..... (version .....) for the above study and have had the opportunity to ask the researcher(s) questions ☐.

2. I understand that my participation is voluntary and that I am free to withdraw from the study at any time, without giving any reason, without my osteopathic care/ medical or legal rights being affected ☐.

3. I understand that sections of any of my patient records may be looked at by responsible individuals from [company/practice/university name] or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records ☐.

4. I agree to take part in the above study ☐.

Name of Patient	Date	Signature
Name of Person taking consent (if different from researcher)	Date	Signature
Researcher	Date	Signature

1 for patient; 1 for researcher; 1 to be kept with osteopathic patient records

Further information can be found at www.nres.npsa.nhs.uk

APPENDIX 15 SPECIMEN PATIENT INFORMATION SHEET

~ GUIDELINES FOR RESEARCHERS ~

The guidance which follows can apply to osteopathic research and/or multi-centre pharmaceutical studies and encompasses the ICH Good Clinical Practice (GCP) guidelines. All researchers writing information sheets within their particular fields, for trials involving patients, patient volunteers and healthy volunteers will find the principles and content helpful. It will also be useful to refer to other guidelines produced for writing patient information sheets.

Potential recruits involved in any research study must be given sufficient information to allow them to decide whether or not they want to participate and what they are agreeing to participate in. An Information Sheet should contain information under the headings given below, where appropriate, and in the order specified. It should be written in simple, non-technical language (avoiding jargon) and be easily understood by a lay person. The use of short words, sentences and paragraphs is preferred.

Consumers for Ethics in Research (CERES) publish a leaflet entitled 'Medical Research and You'. This leaflet gives more information about medical research and looks at some questions potential recruits may want to ask. Copies may be obtained from CERES, PO Box 1365, London N16 0BW or at www.ceres.org.uk/order.htm.

Patient Information Sheets submitted to the Research Ethics Committee (REC) may be headed simply 'Hospital (for NHS research)/Institution/Academic Institution/Osteopathic Practice/GP Practice headed paper'. **If you are the Principal Investigator, the Patient Information Sheet should be printed on local hospital/surgery/osteopathic practice paper with local contact names and telephone numbers before it is submitted to the R&D department of the host organisation for local NHS management approval.**

1. **Study title**

The title should be easy to understand to a lay person. If it is not, a simplified title should be included.

2. **Invitation paragraph**

This should explain that the patient is being asked to take part in a research study. The following is a suitable example:

'You are being invited to take part in a research study. Before you decide if you want to take part, it is important for you to understand why the research is being done and what it will involve for you. Please take time to read the following information carefully and discuss it with others (partner/family members/friends/carer) if you wish. Please ask any of the researchers if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.'

3. **What is the purpose of the study?**

The background and aim of the study should be given here. The duration of the study should also be mentioned.

4. **Why have I been chosen?**

You should explain how and why the patient was chosen and how many other patients will be involved in the study.

5. **Do I have to take part?**

You should explain that taking part in the research study is entirely voluntary. The following paragraph could be used:-

'It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and you will be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive in the future.

6. **What will happen to me if I take part?**

Information should be given to explain how long the patient will be involved in the research, how long the research will last (if this is different), how often they will need to visit a clinic (if this is appropriate) and how long these visits will be. It should be explained whether the patient will need to visit the osteopathic practice/GP practice (or clinic) more often than for his/her usual treatment and if travel expenses are available. What exactly will happen e.g. treatment/examination/blood tests, x-rays, (over and above those involved in standard diagnosis and treatment) or interviews etc.? Whenever possible, a simple flowchart or plan indicating what will happen at each visit should be drawn for the patient. It is also helpful to explain clearly to the patient what you expect of them and what are their responsibilities.

Information should be given concerning the type of research methods intended to be used in the study: the following simple definitions may help:-

Randomised Trial:

Sometimes because we do not know which way of treating patients is best, we need to make comparisons. People will be put into groups and then compared. The groups are selected by a computer which has no information about the individual – i.e. by chance. Patients in each group then have a different treatment and these are compared.

Patients should also be told what chance they have of getting the study's active treatment e.g. a one in four chance.

Blind trial:

In a blind trial you will not know which treatment group you are in. If the trial is a double blind trial, neither you nor your osteopath/doctor will know in which treatment group you are (although, if your osteopath/doctor needs to find out he/she can do so).

Cross-over trial:

In a cross-over trial the groups each have the different treatments in turn. There may be a break between treatments so that the first drugs are cleared from your body before you start the new treatment.

Placebo:

A placebo is a dummy treatment or a dummy pill which resembles the real thing but is not. It contains no active component.

7. **What do I have to do?**

Are there any lifestyle restrictions? The patient should be told if there are any dietary restrictions and whether they can drive, drink, take part in sport or other exercise? The patient should also be told whether they can continue to take their regular medication or whether they should refrain from giving blood? A clear explanation should be given concerning what happens if the patient becomes pregnant.

Where appropriate, it should be explained that the patient should take medication regularly.

8. **What is the procedure/treatment that is being tested?**

A short description of the procedure/treatment approach being tested should be included. Information given should include how frequently the procedure/treatment approach will be administered and the method of administration.

9. **What are the alternatives for diagnosis or treatment?**

For therapeutic research, the patient should be told what other treatments (if any) are available.

10. **What are the side effects of any treatment received when taking part in the study?**

A clear explanation should be given to the patient concerning any possible side effect(s), particularly when a new procedure/treatment is involved. Patients should be encouraged to report whether they suffer and side effects or other symptoms at their next appointment. A contact name and a number to phone should be given to the patient if they become in any way concerned about a side effect or reaction to the study treatment. The name and number of the person to contact in the event of an emergency (if that is different) should also be given.

The known side effects of the study intervention/treatment should be listed in terms the patient will clearly understand (e.g. 'pins and needles' rather than 'paraesthesia').

11. **What are the possible disadvantages and risks of taking part?**

For studies where there could be harm to an unborn child if the patient were pregnant or became pregnant during the study, the following (or similar) should be said:

'It is possible that if the treatment is given to a pregnant woman it will harm the unborn child. Pregnant women must not therefore take part in this study, neither should women who plan to become pregnant during the study. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. Women who could become pregnant must use an effective contraceptive during the course of this study. Any woman who finds that she has become pregnant while taking part in the study should immediately tell her research doctor.'

The pregnancy statement should be used carefully. There are certain circumstances (e.g. terminal illness) where it would be inappropriate and insensitive to bring up pregnancy.

There should also be an appropriate warning and advice for men if the treatment could damage sperm which might therefore lead to a risk of a damaged foetus.

If future insurance status e.g. for life insurance or private medical insurance, could be affected by taking part in the study, this should be stated (if e.g. high blood pressure is detected.) Patients who have private medical insurance should be asked to check with their company before agreeing to take part in the trial to ensure that their participation will not affect their medical insurance.

A statement should be included to outline what will happen in the event that a condition is found of which the patient was unaware. Indications concerning potential problems that could be uncovered and how this information is treated should be made explicit.

12. **What are the possible benefits of taking part?**

Where there is no intended clinical benefit to the patient from taking part in the trial, this should be stated clearly.

It is important not to exaggerate the possible benefits to any patient during the course of the study, e.g. by saying they will be given extra attention. This could be seen as coercive. It would be reasonable to say something similar to:

'We hope that the treatment(s) will help you. However, this cannot be guaranteed. The information we get from this study may help us to treat future patients with (name of condition) better.'

13. **What if new information becomes available?**

If additional information becomes available during the course of the research, the patient will need to be told about this. The following could be used:-

'Sometimes during the course of a research project, new information becomes available about the treatment(s)/drug that is being studied. If this happens, your researcher will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw your research doctor will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

Also, on receiving new information your researcher might consider it to be in your best interest to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue.'

14. **What happens when the research study stops?**

If the treatment will not be available after the research finishes this should be made explicit to the patient; information should be given to them concerning what treatment will be available instead. Occasionally the company sponsoring the research may stop the study. If this is the case the reasons should be explained to the patient.

15. **What if something goes wrong?**

Patients should be informed what procedures are in place to handle any complaints and what redress may be available to them. Is there a procedure in place? A distinction will need to be made between complaints from patients concerning their treatment by members of staff (osteopaths, receptionists, other involved health care professionals etc.) and from something serious happening during or following their participation in the trial i.e. a reportable serious adverse event.

When no-fault compensation arrangements are absent, and the study carries risk of physical or significant psychological harm, the following (or similar) should be said:

'If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal General Osteopathic Council or National Health Service complaints mechanisms should be available to you.'

When there are no-fault compensation arrangements present, the following (or similar) should be included:

'Compensation for any injury caused by taking part in this study will be in accordance with insurance guidelines Your right at law to claim compensation for injury where you can prove negligence is not affected.'

16. **Will my taking part in this study be kept confidential?**

The patient's permission must be obtained to allow restricted access to their medical/osteopathic records and for the information collected about them in the course of the study to be disclosed. It should explain that all information collected about them will be kept strictly confidential. A suggested form of words for company sponsored research is:

'If you consent to take part in the research study, any of your medical/osteopathic records may be inspected by the company sponsoring (and/or the company organising) the research for purposes of analysing the results. They may also be looked at by people from the company and from regulatory authorities to check that

the study is being carried out correctly. Your name, however, will not be disclosed outside the hospital/GP surgery/osteopath's practice.'

Or for other research:-

'All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the practice/surgery/practice will have your name and address removed so that you cannot be recognised from it.'

It is always important to bear in mind that it is the researcher who is responsible for ensuring that when collecting or using data, no contravention of the legal or regulatory requirements of the UK occurs. This is not the responsibility of the REC.

It should be explained that for studies not being conducted by a GP, the patient's own GP will be notified of their participation in the trial. This should include other medical practitioners e.g. consultants not involved in the research who may also be treating the patient. The patient's agreement to do this should be sought. In some instances, agreement from the patient that their GP can be informed is a precondition of entering the trial.

17. **What will happen to the results of the research study?**

Patients should also be told what will happen to the results of the research and when they are likely to be published. When are the results likely to be published? Information concerning where can they obtain a copy of the published results should also be given to the patients. Patients should be informed whether they will eventually be told which arm of the study they were in, but they should be assured that they will not be identified in any report/publication.

18. **Who is organising and funding the research?**

The answer should include the organisation or company sponsoring or funding the research (e.g. Medical Research Council, Pharmaceutical Company, charity, academic institution).

The patient should be told whether the osteopath/doctor/researcher conducting the research is being paid for including and looking after the patient in the study. **This means payment other than that to cover necessary expenses** such as laboratory tests arranged locally by the researcher, or the costs of a research nurse/assistant. You could say:-

'The sponsors of this study will pay (name of osteopath's practice/hospital department/academic institution or research fund) for including you in this study' or

'Your osteopath/ researcher/doctor will be paid for including you in this study.'

19. **Who has reviewed the study?**

It can be helpful to give the name of the Research Ethics Committee which reviewed the study (the members of the Committee, however, should not be listed).

20. **Contact for Further Information**

The patient should be given a contact point for further information. This can be that of an osteopath/researcher/doctor involved in the study.

It shouldn't be forgotten to thank the patient(s) for taking part in the study!

The patient information sheet should be dated and given a version number.

The Patient Information Sheet should clearly state that the patient will be given a copy of the information sheet and a signed consent form to keep.

APPENDIX 16 HOME OFFICE REQUIREMENTS FOR RESEARCH INVOLVING ANIMALS

Scientific experiments on animals are regulated by the Animals (Scientific Procedures) Act, 1986. The Government's position on animals in scientific procedures is described on the Home Office website given below):
www.scienceandresearch.homeoffice.gov.uk/animal-research/animal-welfare

It states (correct at 14-06-05) that:

"The moral objection to the use of animals in scientific procedures is a view held with conviction by some people and is one that the Government respects. However, Parliament has built in considerable safeguards to allow experimentation in limited circumstances and to ensure both proper regulation and monitoring. Although the situation may change in the future, the development of a number of new drugs, and medical and veterinary technologies which help to reduce suffering and prevent large-scale infections among humans and animals continues to depend on this carefully regulated use of animals for testing and research.

Further information can also be found at: www.apc.gov.uk

When osteopaths intend to conduct research to investigate their osteopathic treatment of animals, they should be mindful of the guidelines laid down in:

1. The Veterinary Surgery (exemption) Order 1962 which "allows for the treatment of animals by 'physiotherapy', provided that the animal has first been seen by a veterinary surgeon who has diagnosed the condition and decided that it should be treated by physiotherapy under his/her direction.
2. 'Physiotherapy is interpreted as including all kinds of manipulative therapy. It therefore includes osteopathy and chiropractic but would not, for example, include aromatherapy or acupuncture [ref to Part 1.12 – Your responsibilities in relation to the treatment of animals by non-veterinary surgeons].

Other Complementary Therapists

All other forms of complementary therapy in the treatment of animals, including homeopathy, must be administered by veterinary surgeons. It is illegal, in terms of the Veterinary Surgeons Act 1966, for lay practitioners, however qualified in the human field, to treat animals. At the same time it is incumbent on veterinary surgeons offering any kind of complementary therapy to ensure that they are adequately trained in its application."

Reference: http://www.rcvs.org.uk/Templates/Internal.asp?NodeID=92572

APPENDIX 17 CONTACT DETAILS

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GLOSSARY of TERMS

Adverse Event.
Any untoward medical occurrence in a patient or research study participant which may follow the administration of a treatment/intervention; the untoward occurrence may not necessarily have a causal relationship with this treatment/intervention. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporarily associated with the use of an investigational intervention.

Audit.
A systematic and independent examination of activities related to a research study and documents to determine whether the evaluated study activities were conducted and the data recorded, analysed and accurately reported according to the protocol, sponsor's operating procedures and good clinical practice.

Audit Trail.
Documentation relating to a research study that allows reconstruction of the course of events in a research study.

Chief Investigator (CI).
The Chief Investigator is the person with overall responsibility for the research and all applications must be submitted to the Chief Investigator for their approval before ethics approval is sought.

Coercion.
Any pressure or incentive applied or implied to a patient or healthy volunteer to attempt to gain their agreement to participate in a research study against their wishes. This can include inappropriate inducements or the threat to a patient to withhold access to new or further treatments at a future date.

Confidentiality.
Prevention of disclosure, other than to authorised individuals, of details concerning a research participant.

Consent (Informed Consent).
The formal process by which a research participant agrees to take part in a research study. Informed consent is recorded by written means in able persons or can be verbally or visually recorded. Informed consent can be recorded by an appointed adult (e.g. appointed legal representative, parent or guardian) for a vulnerable person or for a minor. In certain cases, a legally defined minor may give informed consent if they are viewed as mature enough to understand the implications of what they are agreeing to. In order to give informed consent, a research participant must be provided with a

patient information sheet and have the opportunity to ask the researcher(s) for further information about the research study.

Good Clinical Practice (GCP).
A standard for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of a research study that provides that the data and reported results are credible and accurate, and the rights, integrity and confidentiality of research participants are protected.

Legally Appointed Representative.
An individual or judicial or other appointed body authorised under applicable law to consent, on behalf of a prospective research participant, to the participant's involvement in a research study. If a patient appears to become distressed during the research study following the administration of the study intervention, their views override that of the legally appointed representative.

LREC
Local Research Ethics Committee.

Monitoring.
The act of overseeing the progress of a research study, and of ensuring that it is conducted, recorded and reported in accordance with the protocol and (GCP

Main REC
In the case of multi-site studies, the REC undertaking the ethical review of the application. The main REC may or may not be a Type 3 REC depending on the type of research.

NRES.
National Research Ethics Service. This is the organisation through which ethics approval for the conduct of research must be sought if other ethics arrangements are not available to you (e.g. if you are not a student affiliated to a higher education institution). Further information about NRES can be found at www.nres.npsa.nhs.uk.

Participant.
An individual who participates in a trial as part of an active treatment, healthy volunteer or as a control.

Principal Investigator (PI).
The Principal Investigator is the person who is responsible for the research at a designated research site. One Principal Investigator is present at each site.
Protocol.
A document that describes the objective(s), design, methodology, statistical considerations and organisation of a research study. The protocol usually

gives the background and rationale for the study, but these could be provided in the protocol reference documents.

Second REC
The REC that reviews an application on appeal following the issue of an unfavourable opinion by the 'first REC'.

Serious Adverse Event (SAE).
Any untoward occurrence resulting directly from a treatment intervention that:

- results in death
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity

Single ethical opinion
The ethical opinion given by a REC on a research study, with application to the whole of the UK. An ethical opinion may be either favourable or unfavourable.

Sponsor.
An individual, company, academic institution or organisation which takes responsibility for the initiation, management, and/or financing of a research study.

Sponsor-Investigator.
An individual who both initiates and conducts, alone or with others, a research study. The term does not include any person other than an individual (e.g. it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and an investigator.

Vulnerable Subjects.
Individuals whose willingness to volunteer in a research study may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation or of a retaliatory response from senior members within a hierarchical structure (e.g. medical personnel, senior member of a practice, junior personnel in a practice etc). Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic and minority groups, homeless persons, nomads, refugees, minors and those incapable of giving informed consent.