



Professional Papers No 4 Research Activity Guidelines

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Contents

Undertaking research	3
• Facilities for research	
3	
• Computing services	
3	
• Library	3
• Postgraduate research	3
Postgraduate regulations and guidance	
3	
Supervisors	4
Research study	4
• Introduction	4
• Background /Literature review	4
• Objectives/Research question	
4	
• Methods	4
Study design	4
Sample characteristics	
4	
• Data collection	4
Data Protection Act	5
• Ethical Issues	5
• Facilities and costs	5
• References	5
• Subjects	5
• Data and Statistical analysis	5
• How are the subjects selected?	6
• The subject's GP	6
• Informed consent	6
Patient information sheet	6
Consent form	6
Indemnity	6
Dissemination	6

Professional integrity in research	6
Research related misconduct	7
Academic freedom and research	7
Copyright	7
Intellectual property	7
Originality and innovation	7
Protecting authenticity	7
Publication	8
Co-authorship	8
Acknowledgement	8
Declaration of Helsinki	8
Plagiarism	8
Sources of funding	8
• Refund	8
• Externally funded research	8
Research councils and charities	8
Government departments/NHS Trusts	9
Health services research project grants	9
Costings	9
Full Economic Costing	10

The purpose of research is to establish new knowledge, attempt to resolve controversy and consolidate advances in a consensual systematic framework. Scholarship represents the cumulative development of advances personal knowledge and understanding that is the essential foundation for both teaching and further research.

The objectives of research are:

- To deepen and broaden knowledge and understanding by expert responsible and professional means.
- To train new researchers in appropriate methods and relevant professional standards of research.
- To disseminate research results through publication and teaching.
- To secure the exploitation of research results, for the public good and the benefit of professional colleagues.

The responsibility of individual researchers is to conduct and disseminate research of the highest quality that they can achieve, to offer research colleagues the challenge of informed, demanding and productive debate, to inform their teaching through both the product and the process of their research, and to give their students the benefit of sympathetic encouragement and considered judgement.

Undertaking research

Research can be viewed in two ways. First, it is a professional activity with standards of practice, ethical issues and training issues which should all be taken into consideration. Second, it is a business with cost, benefit and training implications.

The benefits of research are:

- Expand knowledge base.
- Improve patient care.
- Improve cost-effectiveness of treatments.
- Develop and/or assess new technologies.
- Facilitate contacts with social services.
- Provide training.

Current research can be hypothesis driven or an investigation of areas of uncertainty.

Facilities for research

These include; an adequately stocked library, an effective computing infrastructure, well equipped laboratories, adequate administrative, computing, technical and clerical support, and adequate accommodation that is appropriately serviced and safe.

Computing services

Researchers need access to information, to fellow researchers and to high quality computing facilities including web access and email facilities.

Library

Access to books and periodicals, archives, electronic information sources, CD ROMs, online datasets such as BIDS, MIMAS, Edina, etc., interlibrary loan service, electronic document delivery facilities.

Postgraduate research

Research done at postgraduate level is regarded as a valuable professional activity.

Postgraduate regulations and guidance

The rights and obligations of postgraduate research students and their supervisors, the regulations governing registration for research, the period of supervised research, submission of theses and dissertations and their examinations are specified in detail in each University handbook for postgraduate research students and supervisors.

Supervisors

Arrangements for supervision will be made usually by the academic heads of department who are responsible for overseeing the supervision received by students after the arrangements have been approved.

Research protocol

Introduction

The introduction provides:

- A context for the research.
- A quick overview of the nature of the issues you are looking at.
- Alerts the reader about what to expect.
- Contains justification for the study.

Background/Literature review

Getting and developing ideas. Searching the literature, library and information systems, the literature search, keeping up-to-date.

Elaborate hypothesis for research – background, preliminary information – pilot studies, audit, survey, sample sized. Redefine hypothesis by discussion with colleagues.

Carry out a thorough literature review. Your topic may already have been exhaustively researched. If that is the case you have the opportunity to rethink your ideas to build on what is already out there. The literature review needs to inform the methods. If the literature review is not thorough it will shine through as an after-thought.

State a few key studies which relate to the research proposal to demonstrate knowledge of the relevant literature in a given topic area. Examine how they are relevant to the proposed study and how your proposed study moves beyond them. Look at the theoretical aspects of these previous studies, e.g. methodology (critical appraisal). You need to demonstrate ability to critically assess the material read for the literature review.

Objectives/Research question

What does your research hope to examine? Clear, specific and concrete objectives that are achievable are necessary. Avoid terminology and define objectives as specifically as possible in order of priority. These objectives may take the form of questions.

Methods

Day to day project management, liaison with colleagues, data collection and storage

Study design

Give a rationale as to why certain methods have been chosen. Describe which methods you are going to adopt, e.g. quantitative design, randomised controlled trial, prospective, retrospective study, attitudinal questionnaire.

Sample characteristics

Inclusion/exclusion criteria: who are you going to include/exclude from your study and why?

Sample selection; what form of sampling are you going to use, e.g. random, convenience or selected? Justify reasons for selecting that sampling type.

How many people are you going to include in your study and how has this been calculated, e.g. power calculation. How are you going to ensure that your sample is representative of the population being studied.

Data collection

What methods are to be used for data collection, e.g. interviews, questionnaires, blood samples? What are the advantages and disadvantages of using these methods? What time scale and where will the research take place. What data will you collect at each visit (include study schedule in appendix if appropriate)?

Data Protection Act

Personal data is information, which relates to living individuals. All researchers using personal data must comply with correct procedures for storage of personal data or processing data in any way for research purposes.

Ethical issues

Will you require ethical approval from the ethics committee? For guidance see the website of the National Research Ethics Service at www.nres.npsa.nhs.uk They state that:

- You must apply to an NHS REC when your research involves;
- NHS patients, i.e. those subjects recruited by virtue of their past or present treatment by the NHS,, including those treated under contract with the private sector.
- Foetal material and in vitro fertilisation involving NHS patients.
- The recently dead in NHS premises.
- Access to records of past and present NHS patients.
- The use of, or potential access to, NHS premises or facilities (including NHS staff).

If you do require ethical approval you need to fill in an ethics application form online at the NRES website. It is advisable to follow their guidelines to the letter.

If you are using patients in your research you will need a patient information sheet and a consent form. The NRES website has guidelines on producing these. These documents should be included in the appendix of your research proposal.

For Orthoptists in the Republic of Ireland, ethical approval can be sought from the local hospital ethical committee.

It is important to adhere to local research governance policies as determined by local Research and Development units in each hospital Trust. Despite obtaining ethical committee approval, research cannot be undertaken without local R&D approval.

Facilities and costs

It is important that your research has no implied cost on the NHS. Think carefully about wording this section bearing in mind what personal time you are going to spend on the research, equipment costs, stationery, etc.

References

List any references that you have made in the literature review or methodology sections taking care to use a recognised system for referencing and keeping the same system throughout.

Subjects

It is important to know the number of subjects to be involved in the study. What is the maximum number of subjects to be recruited?

Data and statistical analysis

What statistics will you use to analyse your results? Will you be receiving help from a statistician? Will your results be entered onto a database? How will you validate your data? State what measurements will be made and how the data will be analysed. A properly constructed trial should have clear evidence of a plan for analysing the observations or measurements.

How are the subjects selected?

Recruitment can be via personal approach, letter, poster, approach via the GP, etc. Inappropriate pressure should not be placed upon subjects to take part. In circumstances where researchers wish to make approaches to subjects with whom they would not otherwise have direct dealings, the initial contact should be made by, or on the authority of, the clinician responsible for the care of the patient.

The subject's GP

It should be regarded as normal medical courtesy to let a GP know that a patient for whom they are responsible has been recruited to a clinical trial. Even when this is not obviously worthwhile, the GP may have background knowledge of the patient that could be relevant to the trial in question.

Informed consent

Patient information sheet

This is required for most studies. It should be written in language that the layman, particularly frightened, sick patients can easily understand and assimilate. It should be headed by a title relating to the study. The title should clearly indicate the nature of the project and the word 'research' should be incorporated. The aim of the information sheet is not to try to discourage participation in the study by graphically describing each and every hazard in minute detail. It should, however, describe any substantial risk for the subject/patient accruing from investigations or procedures being done purely for the study and not as part of their regular management. Hospital contact points and telephone extension numbers of the researchers should be provided. The information sheet should compliment, not replace, a full verbal explanation of the study, and a copy should be given to the participant to keep.

Consent form

For most studies, if not all, formal written consent is required. The consent form should be written in simple non-medical English and should be headed with the title of the study. No attempt should be made to limit the subject's legal rights or release the researcher from liability.

Indemnity

The Health Authority, Trust and individual practitioner must be indemnified against claims and proceedings arising from the study. Orthoptists registered with the British and Irish Orthoptic Society have full insurance cover.

Dissemination

Publications, poster, oral presentation, abstract, peer review, reprints, dealing with correspondence. Further work, new data means new questions, clinical implication of findings, implementation into clinical practice.

Additional information on the research process can be found in the research article section of the BIOS web site.

Professional integrity in research

The Nolan committee on standards in public life has made recommendations to ensure that the highest standards are maintained and are seen to be maintained in key areas of public life. The Nolan committee articulates seven

principles of public life for the benefit of all who serve the public in any way: selflessness, integrity, objectivity, accountability, openness, honesty and leadership. The sum of these principles provides a solid base for the personal integrity that should be reflected in the professional conduct of research.

Everyone involved in research owes a duty of accountability to society, to their profession, to their institution and to the funders of research, to accept full responsibility for the integrity of their own conduct of that research, and for the activities of any staff or students under their direction. This extends to accountability for the ethical basis of research, for the safety of all involved in the research process, for the probity of the financial management of the project, and for seeking to provide optimum value for the public or private funds invested in the project. These responsibilities extend in turn to ensuring the effective management of any agreed timescale for the project, together with the timely provision of any tangible outcomes scheduled to be delivered to an external sponsor.

Research related misconduct

The specific examples of research related misconduct given in the US Commission on Research Integrity recommendations include the following; misappropriation of someone else's intellectual research property by plagiarism or breach of confidence as a reviewer, interference by theft, sequestration or damage of other people's research related property, misrepresentation by deception or lying, obstruction, including with-holding, destroying or falsifying evidence, giving false testimony or influencing witnesses and failing to comply with statutory or institutional regulations.

Academic freedom and research

Academic freedom is the legally established right of members of academic staff to express their opinions without fear of losing their jobs because of other people's hostility to those views. It underpins the right to exercise professional best judgement in the pursuit of knowledge and the conduct of research.

Copyright

This is a legal right which protects creative and intellectual effort. The law relating to copyright is obtained on the Copyright Designs and Patents Act 1988. Copyright only protects against copying. It will not prevent creation of an independent work. Copyright does not protect the idea, simply the expression.

Intellectual property

IP rights are the legal rights associated with creative and intellectual effort or commercial reputation and goodwill. Types of IP rights include patents, copyright, confidential information and know how, trade marks, registered and unregistered design rights, moral rights.

Originality and innovation

New knowledge is by definition original, and curiosity, imagination and tenacity in the pursuit of the perceived logic of experimental and other data are all attributes that are regarded highly in researchers. Originality has two elements: the avoidance of plagiarism and the achievement of innovation.

All publications should be original with respect to the avoidance of plagiarism, but achieving the second will depend on the scholarly or research motivation concerned.

Protecting authenticity

A major assumption about the scientific integrity of research leading to publication is that there should always be a robust and reliable audit trail which can be followed to establish the authenticity of any discovery or invention. The authenticity of records, their provenance and date should therefore be defensible, to support claims both of originality and scientific priority, in the interests of protecting both scientific integrity and the due ownership of intellectual property rights. Advice on suitable practice in this context can be found in guidelines issued by some of the research councils.

Publication

This is the dissemination of the outcomes of scholarship and research in conventional paper form and in other media including electronic media. Along with such artefacts as books, chapters, articles, conference proceedings, reviews, patents, catalogues and other products, software and databases.

Co-authorship

It is in the interests of all authors to disseminate good practice in this area. When submitting manuscripts for publication, a basic assumption is that researchers should know the conventions of authorship in use by the journal they have chosen. The most critical aspect of good practice in this area is the need for authorship and the order of authors to be agreed by the contributors, within the conventions of their discipline(s) before the manuscript is prepared. Standard guidelines on co-authorship were published in the New England Journal of Medicine 1991, 324; 424-428

Honorary co-authorship has sometimes been tolerated by certain groups where inclusion in the list of authors is on the basis not of contributions but rather through other association with the work. This is fraught with the potential for abuse and best avoided.

Acknowledgement

Part of the general ethical obligation of recognition of the work of others is that the contributory efforts of people who have helped in the work being reported should be identified.

Declaration of Helsinki

For research involving human subjects, it is recommended that authors state in the Methods section of their manuscript that their research adhered to the tenets of the Declaration of Helsinki.

Plagiarism

This is the unattributed publication of the work of another as if it were one's own. It is seen by all academic institutions as offensive to norms of research conduct and is therefore often construed as constituting misconduct.

Sources of funding

The Internet is a wonderful resource for looking for funding. The NHS R&D funding site at www.rdinfo.org.uk holds information from over 800 funding bodies. The Association of medical research charities at www.amrc.org.uk holds information on funding for senior clinical, programme grants, travel grants and equipment grants. UK research councils have their own individual websites.

Refund is a publication that is updated monthly provides news of research opportunities including details of application, methods, deadlines and contact names. It can be found on www.refund/ncl.ac.uk

Externally funded research

When targeting funding bodies it is important to clearly identify the area of research and apply appropriately. Less experienced researchers may find it more beneficial to work collaboratively with more experienced researchers as this will improve their chances of being successful.

Research councils

There are six UK research councils: BBSRC, EPSRC, ESRC, MRC, NERC, PPARC.

- Biotechnology and Biological Sciences Research Council
- Engineering and Physical Sciences Research Council
- Economic and Social Research Council
- Medical Research Council
- Natural Environment Research Council
- Science and Technology Facilities council.

Funding is available for both basic and applied research and is usually distributed according to the responsive mode (unsolicited proposals which originate with the researcher) or the conditional mode (proposals which must meet specific criteria). In certain areas the research councils will also provide support through what is known as a managed programme. This may be to support strategic research with specific research aims or to encourage multidisciplinary research.

Charities

Charitable funding is dominated by the major medical research charities such as the Wellcome Trust and the British Heart Foundation. Significant opportunities also exist for funding in the non-medical areas from sources such as the Leverhulme Trust or the Nuffield Foundation. The major charities do not make a contribution towards overheads. Therefore departments should ensure that research with charitable research income can be sustained financially within the department.

Government departments / NHS Trusts

The NHS is a major source of research support and research is funded locally through the NHS Trusts and nationally through the Department of Health and NHS Executive.

Health services research project grants

HS research is broadly defined as the identification and quantification of healthcare needs and the quantitative study of the provision and use of health services to meet them. The research is usually multidisciplinary and involves clinical, epidemiological, social science, economics, operational and management disciplines. Support is usually not provided for clinical trials or

projects concerned with education. Audit based research projects are inadmissible unless the results are likely to have general relevance and applicability.

Costings

All of the direct costs which would be included in a research grant proposal to the research councils should be included in the costing of a proposal to a UK based charity. In addition the following direct costs which are inadmissible in research council proposals must be taken into account when costing an applications to these bodies:

- Estimated cost of inflation on staffing, travel and consumables expenses during the course of the project.
- Services specifically required for the project (computing facilities, hire of equipment, etc).
- Staff recruitment including advertising and removal expenses.
- Staff redundancy claims.
- Fees and training for outside funded staff employed on the project.

The following direct costs must be included when costing research proposals to the UK research councils:

- Salaries, superannuation and national insurance for staff who need to be appointed to work solely on the project.
- Consumables needed exclusively for the project and similar costs such as publishing and specialist journals, equipment maintenance and rental/access charges.
- Equipment which has to be purchased to enable the project to be undertaken including software, spares and installation.
- Travel and subsistence directly associated with the project to enable the project to be undertaken.
- Attendance at relevant conferences.

Full Economic Costs

FEC (Full Economic Costs) is a development of TRAC (the Transparent Approach to Costing) to provide a forecast of the full economic cost of undertaking a research project. In the past, sponsors made varying contributions towards the direct and indirect costs of research projects as outlined above but these were not calculated accurately. A separate contribution towards the indirect costs of some categories of research projects was made to Higher Education Institutions (HEIs) via the HEFCE block grant. Under FEC, all HEIs in the UK are now required to identify all direct and indirect costs for each research project, including space/estates charges, depreciation, an adequate recurring investment for infrastructure, equipment, consumables, travel and the cost of all staff working on the project (including PIs, technical and administrative staff).

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