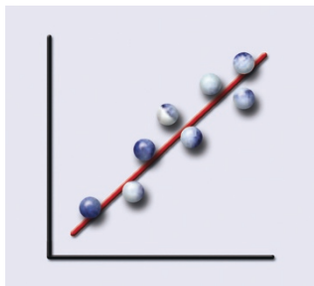
PRACTICE

5

IN BRIEF

- This paper describes three important practical components of the research process: devising a research proposal, seeking external funding for the research and obtaining ethical approval for your proposed study.
- The research proposal provides a justification for and summary of the proposed study. This paper gives an outline of the information required for the proposal.
- Brief details on how to obtain research funding are given, together with advice on resources for practitioners seeking to support their research through external funding.
- An overview of the requirements for research ethics and governance is provided, and a list of resources provided to guide the reader in obtaining ethical approval and research governance.

Research in primary dental care Part 5: Devising a proposal, obtaining funding and ethical considerations



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In previous articles, we have considered how to formulate a research question and choose an appropriate methodological approach to answer that question, including the use of evidence-based research instruments or measurement scales. In this article, we put this information together in the form of a research proposal and consider how to obtain funding for the research project, as well as fulfil ethical requirements.

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WRITING A RESEARCH PROPOSAL

The proposal is essentially a justification and summary of the proposed study and is essential for grant applications and ethical approval.[1] All aspects of the study should be considered before the proposal is written. This includes choosing how to analyse the data, a topic covered in the next article. The overall design will require justification as being the most appropriate way to answer the research question. It is essential to obtain help from experienced researchers when putting together a research proposal.

All proposals have a similar structure. They should include a review of the literature, clearly outlining the rationale for the project, its aims and objectives, the study design and methods, ethical considerations, the potential benefits of the study, a time schedule, a budget, and a plan for the dissemination of the results. The format for a typical research proposal is outlined in Fig. 1.[1,2]

FUNDING A RESEARCH PROJECT

Ensuring adequate funding for research projects is a pre-requisite for successful research. It is integral to the research process and therefore advice should be obtained at an early stage from the research co-ordinator/academic department/research network which is supporting you. Preparing a budget involves considering carefully the duration of the project and your time commitment to it, as well as the obvious costs of surgery expenses, laboratory fees, consumables, equipment, staff costs, patients costs, other professional fees, travel and subsistence costs and other overheads.[3]

Funding can be obtained from dental bodies, manufacturers, the Department of Health's Research and Development programme and other sources (*see* Table 1).[3] First-time researchers should consider collaborating with established successful researchers when applying for funding as the process requires expertise and experience.

Most funding bodies have their own grant application forms and provide guidance for applicants. It is essential to use the format expected by that particular organisation. A grant application normally consists of several sections and will cover areas similar to the research proposal outlined in Fig.1. It should particularly emphasise the relevance of the project to the particular funding body.

Not all grant applications are funder-initiated. It is advantageous to dental product manufacturers to have their products tested in the 'real world' of general dental practice, and such manufacturers may fund research projects if GDPs approach them, demonstrating that they have the necessary skills and support to undertake research.

ETHICAL CONSIDERATIONS

Ethical approval

Ethical approval from an appropriate research ethics committee (*see* Table 1) is currently required if your research involves:[4]

- Patients and users of the NHS
- Individuals identified as research participants

Fig. 1 Structure of a typical research proposal

1. **Title of the study**
2. **Principle investigators** – names and contact details
3. **Advisors, statisticians, and other organisations such as laboratories involved in the study** – names and contact details
4. **Research question** – include its social and scientific relevance and justify the study
5. **Background of the project** – detail and critically review the referenced literature relevant to the research problem
6. **Aims and objectives**
7. **State hypothesis** (if appropriate)
8. **Study design** – description of important elements of the methods. May include:
   - Type of study eg qualitative/quantitative, prospective/retrospective, survey, randomised controlled trial etc.
   - Dependent/independent/confounding variables
   - Description of the study population from which samples will be drawn
   - Recruitment of subjects to the study
   - Sampling methods and inclusion/exclusion criteria
   - Sample size and justification (power calculation)
   - Number of groups studied
   - Group allocation
   - Blinding of subjects/investigators
   - The unit of analysis eg patient, group, tooth
   - Details of study intervention eg treatment, investigation, interview
   - Measurement instruments and their justification
   - End-points
   - Plan of procedures eg order, site, timing, frequency, information given, equipment used, storage of samples etc.
   - Methods to reduce bias
   - Methods to reduce hazards and risks and deal with potential problems (could be included in research governance – see later)
   - Planned analyses, statistical tests, level of significance, method of data entry and data analysis package to be used
9. **Ethical issues and research governance** eg research sponsor, risk limitation, data protection etc.
10. **Details of resource requirements and budget**
11. **Time schedule**
12. **Expected outcomes and benefits of the study**
13. **Dissemination of results**
14. **Forms** – data collection sheets, laboratory forms, patient information sheets, consent forms, questionnaires etc.

because they are relatives or carers of patients and users of the NHS
- Access to data of past and present NHS patients
- The use of, or potential access to NHS premises or facilities
- NHS staff recruited as research participants by virtue of their professional role.

Ethical approval is not usually required for audit projects which do not require input from the patients. Since obtaining approval for a study can take weeks it is worth obtaining advice from your local research ethics committee about whether ethical approval is necessary at an early stage in the design process. The relevant forms should be obtained from your local research ethics committee (*see* Table 1) and, as with every stage of the research process, it is important to get the forms checked by an experienced researcher before submission to avoid unnecessary delays. If a multi-centre study is being proposed, you should make submission to a multi-centred research ethics committee (*see* Table 1). It is important to remember that ethical approval must be obtained before the study is piloted. After approval has been granted, you may need to make amendments to the protocol as a result of your pilot study. It is necessary to inform the ethical committee of any changes you have made.

Research governance

Research governance is about putting into place quality assurance systems for research, and, like clinical governance, is a legal requirement. It adds an extra tier to the procedures for establishing a research project and brings into further scrutiny research that involves patients. The Department of Health's Research Governance Framework for Health and Social Care[5] sets standards for research undertaken in the NHS, defines mechanisms to deliver, monitor and assess standards, and outlines what responsibilities have to be met and by whom. The aim is to improve research quality and safeguards for the public.

It should be assumed that for any research project that is undertaken, the research must be carried out in accordance with the research governance framework.

All research projects should have a sponsor. A sponsor can be:

- The funding organisation for the project
- A local academic department
- The lead primary care trust (PCT) for research governance in your area
- The lead health or social care organisation for the project
- The researchers' employer
- The local primary care research network.

The sponsor takes primary responsibility for ensuring that arrangements are in place to ensure the appropriate conduct and quality of the study. For example, it will check whether the proposal has been properly assessed by independent experts, whether the research will be carried out in a suitable location with appropriate resources, and what procedures are in place to ensure data protection, health and safety and other aspects of risk management.

All persons involved in the project have research governance responsibilities listed in the framework document. Those dentists taking on the role of leading a project have particular responsibilities regarding the conduct of the study; these relate to health and safety issues, legal and ethical requirements, data protection, good communication, financial management and dissemination of the results through the appropriate channels. Do not forget to check with your medical defence organisation that you have suitable medico-legal cover to undertake the research. Research governance involves a lot

of paper work and, as with clinical governance, all procedures should be documented.

Most of the legal issues pertaining to the storage of research data arise out of the Data Protection Act.[6] The Act places restrictions on the storage of any data in which the individual could be identified. It also places restrictions on the analysis of data for purposes other than that for which it was originally intended. If you are storing information about patients on a computer then you must ensure that the study has been registered with the local data protection officer. It is important that none of the data should be able to be traced back to individual subjects.

Participant confidentiality can be facilitated by using unique subject ID codes to identify participants, rather than their names. A list of the ID codes and the participant identifiable data should be held in a separate spreadsheet or database from the study data so that information cannot be attributed to individuals. The two lists can then be linked by the ID codes. If the data are stored on a computer then access to the data should be password-protected and limited to individuals involved in the data collection process.

The lead PCT for research governance in your area will be the usual point of contact with regard to instigating research governance procedures for a project conducted in general dental practice. A lead PCT will usually take on research governance responsibilities on behalf of several other local PCTs. See Table 1 for contact details.

SUMMARY

This article has described some of the practical aspects of the research process – how to put together a research proposal, obtain funding for the research project, and fulfil ethical requirements. These elements are essential for ensuring that research is relevant, well planned, of high quality and safe. The next step in the research process involves piloting the study to expose any problems with the research protocol, followed by the main period of data collection. In the next article we will consider how to analyse the data.

Table 1 Further information

Writing a research proposal

There is helpful advice on writing research proposals via the research process flowchart available at: **www.rddirect.org.uk**

Practical advice is also available via RDDirect, a telephone research advisory service on 0113 295 1122, or E-mail: info@rddirect.org.uk or look on the RDDirect website at: **www.rddirect.org.uk**

For advice on what should be included in patient information sheets, contact your Local Research Ethics Committee (see below) who will usually provide written guidance.

See also Chapter 6 of Bowling A. *Research methods in health: investigating health and health services.* Buckingham: Open University Press, 2002.

Funding

A national database of funding sources and awards for research in health and related areas is found at: **www.rdinfo.org.uk**

To find out about current research projects and the funding they have received visit the National Research Register: **www.update-software.com/national/**

The 'Research in General Dental Practice' leaflets produced by the Faculty of General Dental Practitioners (UK) give further information on budgeting, finance and grantsmanship. For more information see: **www.rcseng.ac.uk/dental/fgdp/#research**

or call the Research Officer on 0207 869 6752 or E-mail: lee.smith@rcseng.ac.uk

Ethical approval

The Central Office for Research Ethics Committees (COREC) provides information on applying for ethical approval, outlines which research studies require approval, and gives details of local research ethics committees and multi-centre research ethics committees: **www.corec.org.uk**

For a list of local research ethics committees see: **www.corec.org.uk/LRECContacts.htm**

If your project is based in an academic department or a hospital trust, you should first approach the ethics committee within that academic institution or Trust for advice about ethical approval.

Research governance

The Research Governance Framework for Health and Social Care for England, Wales, N.Ireland and Scotland can be accessed at: **www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/ResearchAndDevelopmentAZ/ResearchGovernance/fs/en**

A useful summary of the roles and responsibilities of researchers, funding bodies and sponsors is outlined in:

Taylor M. Research governance. *Health and Social Care in the Community* 2002; **10:** 6-9.

The Royal College of General Practitioners has very helpful research governance information under its 'research' section: **www.rcgp.org.uk**

Contact your local PCT for information on the lead PCT for research governance in your area. For a list of PCTs and hospital trusts, please see: **www.nhs.uk**

Information on the implications of the data protection act for researchers can be found at: **www.informationcommissioner.gov.uk**

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