National Council for NCOR Osteopathic Research

**RESEARCH IDEA – REQUIRED INFORMATION AND CHECKLIST (May 2013)**

So, you are interested in undertaking some research, there are a few things you need to think about before taking the next step.

If you plan to approach any organisation for potential collaboration, advice or funding for your study idea, they will want to have a clear idea of what you plan to do.

The following information is intended to help you prepare the information that you would need to provide when communicating with anyone who may have an interest in your project.

**Key points**

Have you clearly defined your research question?

Can you say why the question is important?

Think **PICO:**

**P**opulation: Describe your population of interest.

**I**ntervention: What is the treatment you want to research?

**C**omparator group: What can you compare your intervention/treatment with?

**O**utcomes: How are you going to measure effects or outcomes?

**Background and Rationale**

First of all you need to portray the importance of your research idea. This should be achieved with a brief literature review, outlining the problem being addressed by your proposed research and how your project is likely to add to the body of knowledge in this area. You should detail why the research is important in terms of benefits to patients and, if applicable, the NHS. You should also consider and explain why the research is important at this particular time, and know that this type of work is not being undertaken currently by other researchers.

**Your proposed research project**

You will need to provide an expert summary of your proposed research project, which outlines the main elements of your project design.

*Design*

Provide a brief statement of the study design you will use, for example, a randomised controlled trial. We have information about some study designs in our learning online section, and we will add more to this section: www.ncor.org.uk/learning-online/evidence-based-tutorials/

*Setting*

If you plan to collect primary data, as opposed to researching existing literature (secondary data), you will need to describe the health service setting(s) for your research. For example, patients in a private osteopathy practice, GP practice, or hospital setting.

*Strategy for reviewing literature*

You will need to conduct a literature review, whether or not this is the main focus of your study. In primary data collection studies, the literature review serves as a form of modelling for the study. It will inform the development of the research question as well as various elements of the methodology (ref). For example, the literature can help you to justify the outcome measures that you choose to use; it may also highlight the availability of existing survey or data collection tools which could be used in your study. The quality of relevant literature must be assessed and you should explain the search method and criteria used for this process.

*Target population*

You need to define the population you wish to study, for example, patients with tension-type headache or chronic low back pain. You should define this population using recognised classification or diagnosis criteria. For instance, using classifications for headaches published by the International Headache Society (http://www.ihs-headache.org/ ) to define your study population.

*Describe the intervention*

The intervention you are assessing in your project must be clear. For example, if you are assessing the effectiveness of osteopathic treatment you will need to define osteopathy and also each of the techniques that you will use and why. Describing them in detail is important in order to make the study repeatable. If the treatment/intervention is likely to vary then you should explain how you will deal with this.

*Comparator group*

If you want to investigate whether a treatment or intervention is useful you will need to have some confidence that the outcomes occur as a result of the treatment, not some other factor(s) e.g. natural recovery, or environmental effects. To achieve this you can compare those who receive the intervention with a control group(s), as in a randomised controlled trial. Comparisons are normally made with people receiving standard care or another existing intervention, a placebo, no treatment at all, or being on a waiting list to receive treatment in the future. Many trials use a number of comparisons, for example, treatment compared with another treatment and no treatment. For more information about randomised controlled trials you can read our evidence-based practice tutorial: http://www.ncor.org.uk/wp-content/uploads/2012/12/RCTs_intro.pdf

You will need to describe your comparator group(s), justifying your choices, and describe your randomisation method.

*Outcome measures and costs*

In order to objectively measure how well your intervention works, you will need to use a standardised outcome measure(s). Outcome measures are a way of establishing changes following a treatment/intervention. For example, measuring pain using a visual analogue scale before osteopathic treatment and again after each treatment is a way of measuring changes in pain levels. You can read more about outcome measures here: http://www.ncor.org.uk/wpcontent/uploads/2012/12/outcome_measures.pdf

When presenting the outcome measures you intend to use, you must include a justification for your choice, particularly when there are a number you can choose from. Considering outcomes used in previous studies is extremely important; consistency in the use of outcome measures allows systematic reviewers to combine the results of numerous studies, therefore increasing the statistical power of results (ref – COMET initiative). The COMET Initiative has a database of Core Outcomes for various interventions and patient populations: www.comet-initiative.org.

In studies where there is a health economic component, you should state from what perspective costs and benefits will be considered and how you plan to collect this information.

*Sample size*

Those who are likely to be interested in your project will want to know how many people you intend to include in your study. They will also want to know if the results of your study are likely to be meaningful in a statistical sense and this will depend on your sample size. You should therefore calculate the sample size required for your study and include this in your proposal along with the estimated effect size, power and/or precision used in the calculation.

*Recruitment of participants*

You will need to make it clear how you plan to recruit participants for your study (where applicable). If you are hoping to involve existing patients in some research, they must be made fully aware of the research through receipt of a participant information sheet, and sign a consent form agreeing to be part of the study. If you are planning to recruit participants who are NHS patients, this will involve a different level of consideration and ethical permission.

Recruitment methods can take many forms, and this can include via advertisements, or through referral. The type of recruitment and any inclusion and exclusion criteria must be considered prior to any research.

*Ethics and research*

Different types of investigation can take place within a practice, and some of these will require ethics approval. If you are unsure whether your work needs ethics approval before it can proceed, you should look at the table produced by the National Research Ethics Service (http://www.nres.nhs.uk/EasySiteWeb/GatewayLink.aspx?alId=355).

*Project timetables including recruitment rate*

Another key piece of information to provide is the length of the study. You will need to justify your estimation of the duration of the entire study and outline the main stages with the expected duration of each. You should also detail the expected recruitment rate i.e. how long it will take to recruit x number of participants. You could use a Gantt chart to present all of the above information clearly. You can read about Gantt charts here: http://books.google.co.uk/books?id=JdFDQzqPbzEC&pg=PA281&dq=health+Research+project+planning+gantt&hl=en&sa=X&ei=e9SMUb3YEeaW0AWW3oH4Aw&ved=0CD0Q6AEwAQ#v=onepage&q=health%20Research%20project%20planning%20gantt&f=false

*Flow diagram*

A flow diagram is useful, and sometimes required by funding organisations to provide a visual representation of your study proposal.

*Expertise in team*

Undertaking a research project requires a number of skills, so a multidisciplinary team is often required. You may need a statistician to help you with sampling, for example. Once you have established which skills will be needed for your project you can then start to build your team. Once you have agreed a team you can give interested parties confidence in your combined ability to undertake the project.

You will need to provide personal details of all persons involved in the proposed research, their research experience, and include the extent and nature of their contribution. Those with other supporting roles, such as administrative authority, a finance officer, head of department and/or sponsor should also be included.

You must declare any conflicts or potential conflicts of interest relating to any of our team members. This is required to avoid any perception of bias or potential embarrassment to any party involved with the project.

*Abstract in plain English*

You should provide a summary of your proposed research that can be easily understood by a wider audience so that non-experts in your subject area can understand what your intended project involves. This helps commissioners of research to decide whether or not your proposal is the best one to answer a specific problem or brief. You must explain specialised technical terms and acronyms and avoid using discipline-specific jargon.

If you are responding to an advertised/commissioned call, you should explain how your research proposal is relevant to the research question.

Some guidance on writing in plain English can be found here: http://www.plainenglish.co.uk/free-guides.html

**Now that you have thought about and described your project in detail, there are just a few more things to consider:**

**Patient and Public Involvement**

Patients and the public can be involved at various stages in the research process, not only as participants in a trial. The extent of their involvement is likely to vary depending on the nature and context of your study. Patients and the public may be involved in identifying research topics, prioritising research questions, assisting in the design, or carrying out the research. You should explain if and why you have or haven't involved patients and the public in your proposal. You will then need to explain how they will be involved.

**History of Application**

Submitting proposals to more than one funding body at a time is not acceptable practice. If you have previously submitted the same or a similar proposal for consideration to an organisation you must disclose any information regarding these, as failure to do so may be viewed as academic misconduct.

**Dissemination and Outputs**

Describe the way(s) in which you plan to disseminate the research you propose and the expected output of the research and the subsequent impact. This information assists the funding organisation in deciding whether or not your research will provide value for money.

## Final checklist

**Background and Rationale**

Why is your research important? Back this up with relevant literature.

**Design**

What kind of study is it?

**Setting**

In what kind of health setting will your study take place?

**Strategy for reviewing literature**

How will you conduct the literature review that will inform your study design? How will you assess the quality of the literature?

**Target population**

Describe your study population.

**Intervention**

Describe, in detail, the intervention.

**Comparator group**

Describe your comparator group(s).

**Outcome measures and costs**

How will you measure the outcomes of your intervention? Justify your choice of outcome measures. How will you measure cost, if applicable?

**Sample size**

What is your sample size? Show your calculations.

**Recruitment of participants**

How will you recruit participants for your study?

**Ethics and Research**

Does your study require ethics approval?

**Project timetable**

How long will the study take? What will happen when?

**Flow diagram**

Present your study using a flow diagram.

**The study team**

Describe the expertise of your team.

**Abstract in plain English**

Write an abstract in plain English

**Patient and public involvement**

How will patients and the public be involved in your study?

**History of application**

Have you applied for funding elsewhere?

**Dissemination and outputs**

How will you disseminate your research findings? What impact will they have?

Once you have a tick next to each box and you have prepared all of the relevant information we would be happy to look over your proposal and make comments and suggestions. You can contact us via the website: www.ncor.org.uk/contact-us/ or you can phone us on 020 7882 6131.